POINT OF CARE
TESTING

Roche *OMNI C*

Reference Manual

Roche

Roche Diagnostics GmbH
D-68298 Mannheim / Germany

www.roche.com

Copyright © 2003 Roche Diagnostics GmbH, all rights reserved

The contents of this document may not be reproduced in any form or communicated to any third party without the prior written consent of Roche Diagnostics. While every effort is made to ensure its correctness, Roche Diagnostics assumes no responsibility for errors or omissions which may occur in this document. Subject to change without notice.

REF/No. 03261018001

Rev. 5.0, Juli 2003

CE IVD

First edition: October 2001

– Important information! – Always follow! –

This **Reference Manual** contains vital **warning and safety information**.

This instrument is intended to be used only for the specialized purpose described in the instructions. The most important prerequisites for use, operation, and safety are explained to ensure smooth operation. No warranty or liability claims will be covered if the instrument is used in ways other than those described or if the necessary prerequisites and safety measures are not observed.

The instrument may be operated only by persons whose qualifications enable them to comply with the safety measures that are necessary during operation of the machine.

Adjustments and maintenance performed with removed covers and connected power may be attempted only by a qualified technician who is aware of the associated dangers.

Instrument repairs are only to be performed by the manufacturer or qualified service personnel.

Only accessories and supplies either delivered by or approved by Roche are to be used with the instrument. These items are manufactured especially for use with this instrument and meet the highest quality requirements.

Operation of the instrument with solutions whose composition is not consistent with that of the original solutions can negatively affect, above all, the long-term measurement accuracy. Deviations in the composition of the solutions can also decrease the service life of the electrodes.

The quality control requirements must be completed at least once daily for safety reasons. Because accurate measurement results depend not only on the proper functioning of the instrument, but also on a number of other factors (such as preanalytics), the results produced by the instrument should be examined by a trained expert before subsequent decisions are reached that are based on the measurement values.

Explanation:

Meaning: "Caution, refer to accompanying documents“.

– Important information! – Always follow! –

– Operating safety information –

- The instrument has been constructed and tested according to the protective measures stipulated by EN 61010-1: 1993 / IEC 1010-1 for electrical measurement, control, IVD, and laboratory instruments and was delivered from the factory in flawless condition with regards to safety features. In order to preserve this condition and ensure safe operation, the user must respect the notices and warnings that are contained in these Instructions for Use.

- This instrument is classified under the protection class I according to EN 61010-1 / IEC 1010-1.

- The instrument meets the conditions for overvoltage category II.

- The instrument meets the conditions for contamination level 2.

- Do not operate the instrument in an explosive environment or in the vicinity of explosive anesthetic mixtures containing oxygen or nitrous oxide.

- If an object or liquid enters the internal areas of the instrument, remove the instrument from its power supply and allow an expert to check it thoroughly before using it again.

- The instrument is suitable for long-term operation indoors.

CAUTION:

- The power cord may be plugged into a grounded socket only. When using an extension cord, make sure it is properly grounded.

- Any rupture of the ground lead inside or outside the instrument or a loose ground connection may result in hazardous operating conditions. Intentional disconnection of the grounding is not permitted.

- The instrument is not suitable for operation with a direct current power supply.
  Use only the original mains plug delivered with the Roche OMNI C.

– Operating safety information –

1 Introduction

2 Specifications

3 Operating modes

4 Performance data

5 Trouble shooting

6 Interfaces

7 Theoretical foundations

8 Appendix

9 Index

1 Introduction

1.1 General notes 1-1

1.1.1 General operating instructions 1-1

1.1.2 Symbols 1-1

1.2 Safety instructions for specific dangers 1-2

1.2.1 Disposal of waste water, bottles, electrodes, and the instrument 1-2

1.2.2 Decontamination 1-2

1 Introduction

1.1 General notes

1.1.1 General operating instructions

The Roche OMNI C should be enabled at all times!

Always perform shutdown procedures when the instrument will remain switched off for a longer period of time (longer than 24 hours). For additional information, please see the Instructions for Use, chapter 1 "**Introduction**", section "**Shutdown**").

Avoid leakage of fluids inside the analyzer.

Complete at least one quality control test every day (please see the Instructions for Use, chapter 5 , "**Quality control**", for more information) in order to quickly recognize error functions in the Roche OMNI C.

1.1.2 Symbols

Reference manual

All sections / passages that are marked with this symbol (refer to Instructions for Use) describe information to avoid possible potential for personal injury (for patients, user or third person)

Risk of infection!

All sections / passages that are marked with this symbol describe procedures and/or indicate conditions or dangers that could damage or lead to a malfunction in the Roche OMNI C, and which therefore should never be attempted.

TIP: All sections / text locations marked with "TIP" describe safe procedures that are intended to provide the user with additional "Help."

1.2 Safety instructions for specific dangers

1.2.1 Disposal of waste water, bottles, electrodes, and the instrument

Dispose of the waste container in accordance with local regulations for hazardous waste.

1.2.2 Decontamination

After use, components of the Roche OMNI C, including tubing, waste container, filling port, etc., contain biological fluids and represent therefore a possible infectious risk. Handle these components with care and avoid contact with skin.

Always wear gloves!

The purpose of this procedure is to minimize risk when replacing items that were in contact with biological samples.

Roche recommends following a decontamination procedure in addition to regulations specific to the laboratory.

These decontamination procedures should be performed periodically to minimize the risk of infections.

For more detailed information about decontamination, see the chapter "Maintenance" in the Instructions for Use.

2 System description and functionality

2.1 Screen 2-1

2.1.1 Screen arrangement 2-1

2.1.2 Header line 2-2

2.1.3 Parallel operating modes 2-3

2.1.4 Status line 2-4

2.2 Printer 2-4

2.3 Measuring chamber 2-5

2.3.1 Electrodes 2-5

2.3.2 tHb/SO_2 module 2-6

2.4 Sample port module 2-6

2.5 Pump 2-7

2.6 Bottle compartment 2-8

2.6.1 Bottle compartment cover 2-8

2.7 Reverse side 2-8

2.8 Instrument cover 2-9

2.9 Tubing system 2-9

2 System description

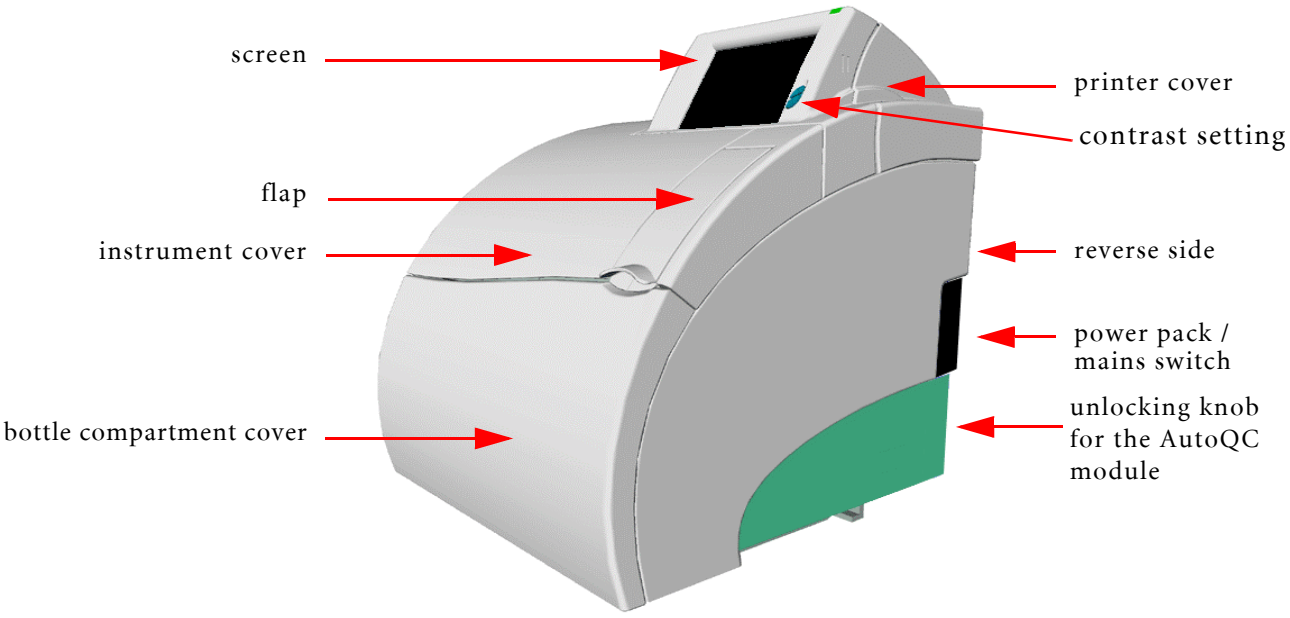


Fig. 1

2.1 Screen

All information (results, error messages, warnings, etc.) is displayed on the screen. The screen consists of a 5.7" colour LCD that is covered with a touch-sensitive film.

2.1.1 Screen arrangement

The Roche OMNI C screen is divided into three main areas:

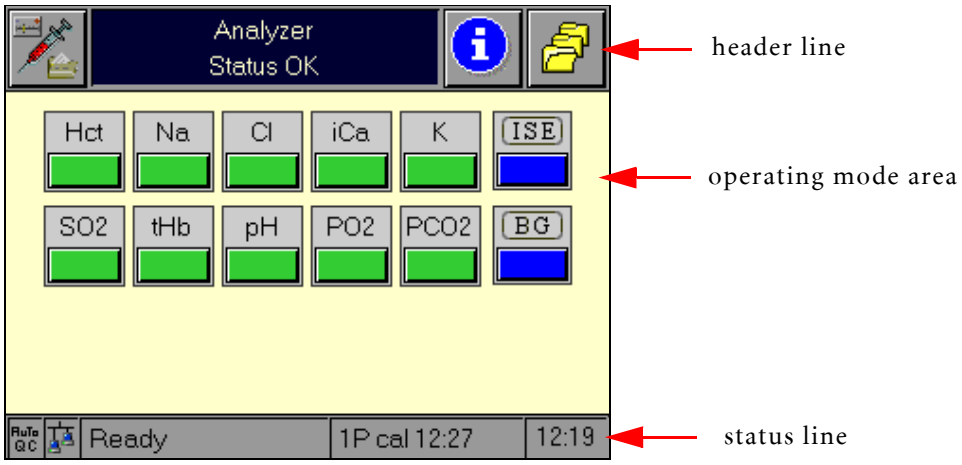


Fig. 2

This screen division applies to all areas of the Roche OMNI C software. The header and status lines are always available in the same division, the operating mode area depicts the status of the currently active operating mode and serves the interaction of the operating modes with the user.

2.1.2 Header line

The header line contains the following elements:

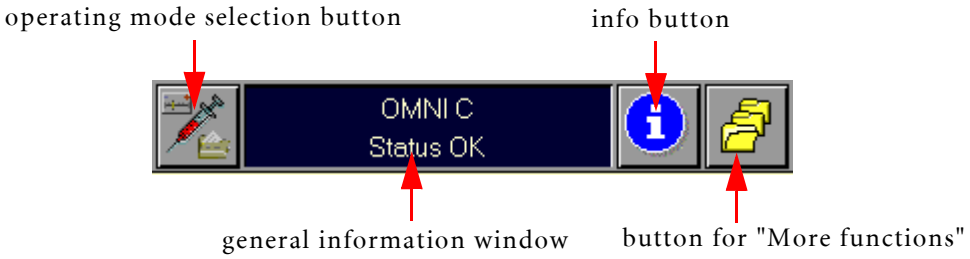


Fig. 3

The **operating mode selection button** enables switching between the individual operating modes: Analyzer, Database, and Setup.

Pressing one of these buttons initiates a switch to the desired operating mode.

The menu times out after 5 seconds. In other words, when the user does not take any action, the menu disappears automatically after this length of time. Pressing the operating mode selection button again while the menu is visible closes the menu. Upon selection of an operating mode, the display switches to the corresponding side of the screen.

The **info button** activates the Info operating mode. The Info operating mode has a special status because it is virtually superimposed on top of the other operating modes. The Info operating mode contains information on everything that could be associated with the instrument, specifically all status information (fill levels, electrodes, log entries), user information, and on-line help. Upon exit, the Info operating mode terminates completely.

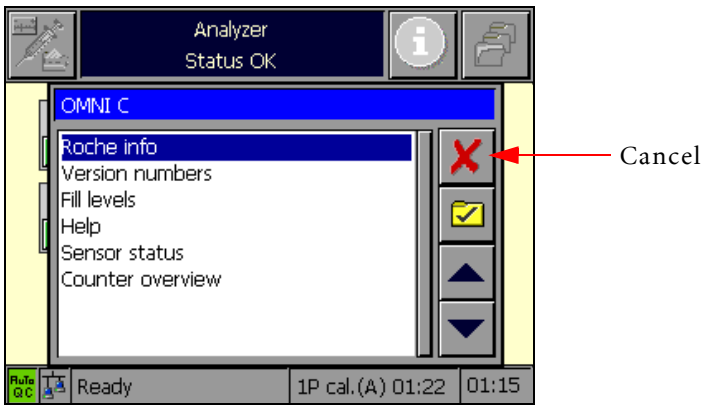


Fig. 4

The button calls up a window with which the following functions may be activated:

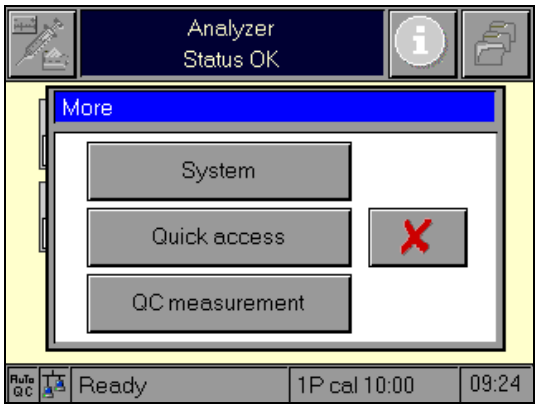


Fig. 5

The keys are used for navigation through various operating modes or to functions in the current view. The "Cancel" button or a timeout closes the window without action.

The currently active operating mode uses the **general information window** to display navigation notes and/or detailed information about the displayed window.

2.1.3 Parallel operating modes

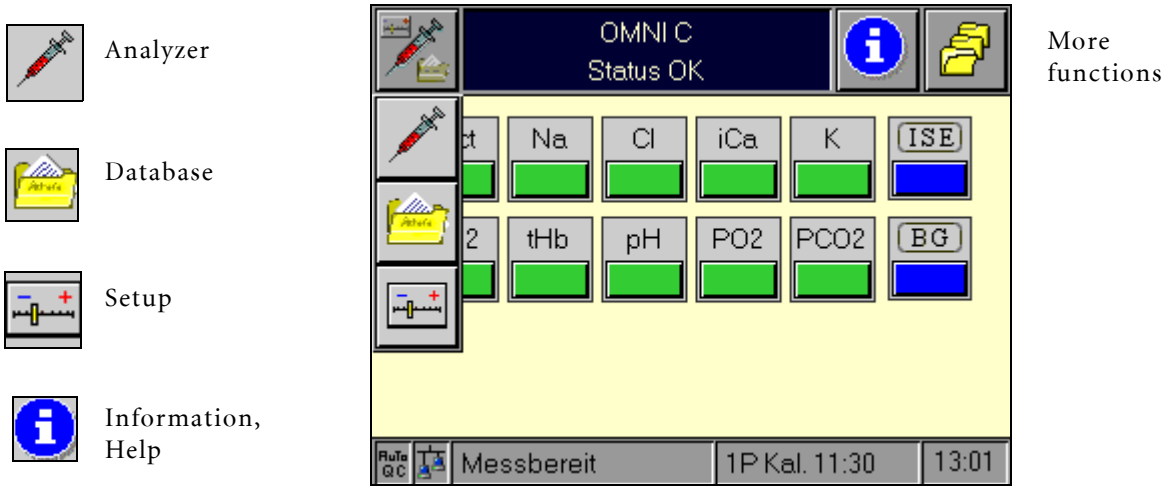


Fig. 6

For more detailed information about the operating modes, please see the respective chapters in this Reference Manual or in the Instructions for Use.

2.1.4 Status line

The status line permanently displays information about the Analyzer operating mode. The following information is displayed :

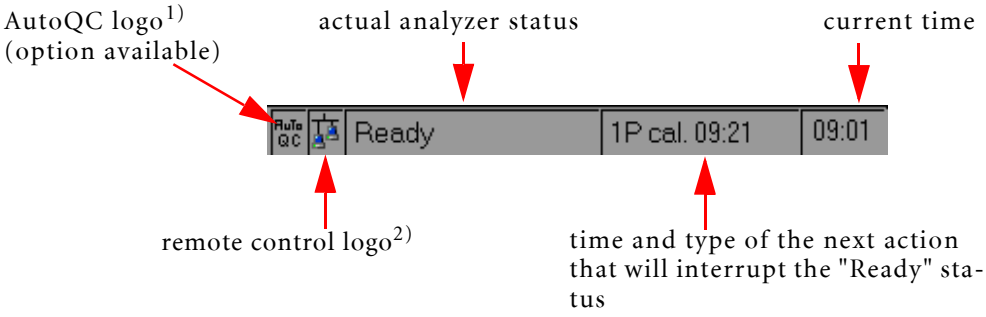


Fig. 7

1) Logo background: green: activated and ready
red: activated, not ready
gray: not installed

2)Logo background: green: connected
gray: not connected

2.2 Printer

Low-noise 2" thermal printer with integrated paper cutter.

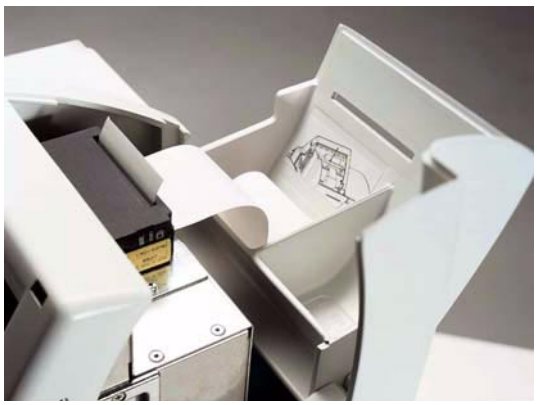


Fig. 8

TIP: The printer paper is heat sensitive on one side only.

Please be certain that you insert the thermal paper correctly! Observe the instructions on the label on the inside of the printer cover.

2.3 Measuring chamber

The measuring chamber consists of the following components

- **Electrical ground contact**: grounds electrode amplifier's electrical currents.
- **tHb/SO_2** module: see section 2.3.2!
- **Valve V3, V5**: these valves serve to control the transport of fluid.
- **Sample sensors SS1, SS2**: these two sensors are located under the black sample sensor covering plate. They detect the operating fluids and the sample.
- Tubing
- **Measuring chamber trough**: this is held at 37 °C. The electrodes are pushed through the spring contacts against the retainers into the socket.
- **Measuring chamber cover**: it is held at 37 °C, contains the electrode window and the switching magnet for the measuring chamber cover sensor.
- **Contact bank**: the contact bank contains the replaceable spring contacts for the electrodes and the cover sensor. The electrode amplifiers are located behind the contact bank.
  A colour-coded strip is located above the contact bank and is used to identify the electrodes.
- **Left retainer**: serves to secure the electrodes as well as the tubes used with the reference electrode.
- **Locking lever**: movable part of the left retainer.

2.3.1 Electrodes

The correct positions of the various electrodes are easy to determine by the colours on their contact caps and/or by their labelling (see "Contact bank").

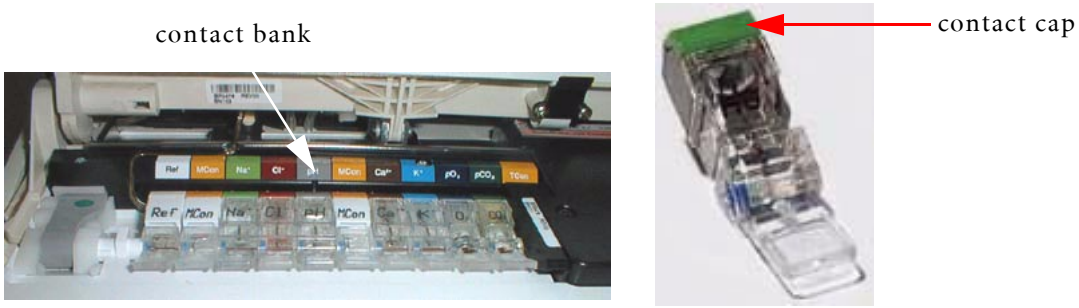


Fig. 9

Colours of the electrode contact caps:

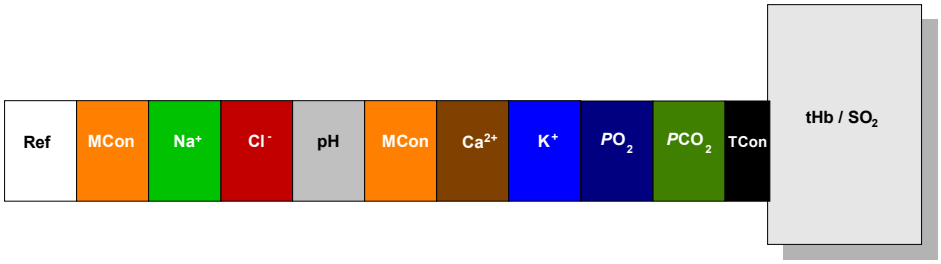


Fig. 10

2.3.2 tHb/SO_2 module

The tHb/SO_2 module is an optical sensor module for determining the levels of total hemoglobin (tHb) and oxygen saturation (SO_2) in whole blood.

Fig. 11

The complete module is sealed and calibrated at the factory ("Factory setting") and may be exchanged only as a complete unit.

Never open the module!

2.4 Sample port module

The sample port module consists of the flap, the fill port holder (including fill port), the needle and the sample drip tray.

Flap

When opening the flap, notice two definitive locking positions:

- Flap position 1 (half opened) – **syringe mode—for syringes and ampoules**

syringe

ampoule

Fig. 12

- Flap position 2 (completely opened) – **Capillary mode—for capillaries and Roche MICROSAMPLERS**

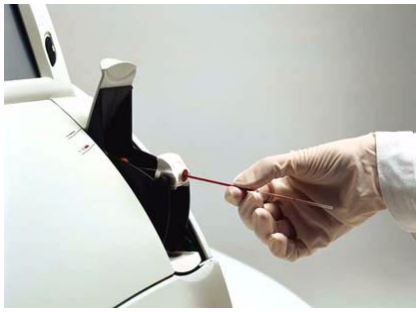
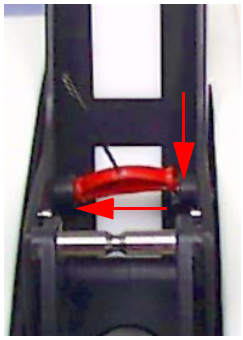


Fig. 13

Needle, fill port holder with fill port and sample drip tray



suction tube

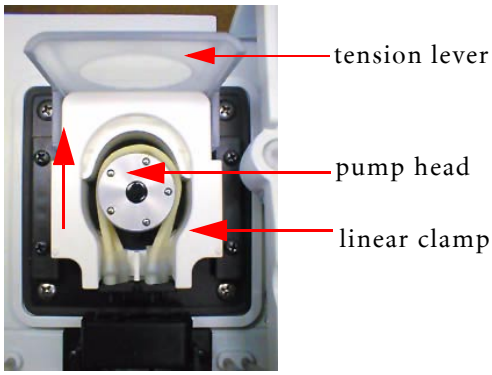
fill port holder and fill port

sample drip tray

Fig. 14

2.5 Pump

The peristaltic pump transports the sample and the operating fluids inside the instrument.



pump open

pump closed

Fig. 15

2.6 Bottle compartment

Fig. 16

2.6.1 Bottle compartment cover

A microswitch detects the status of the cover (open / closed).

The following image appears when the cover is opened (bottle exchange):

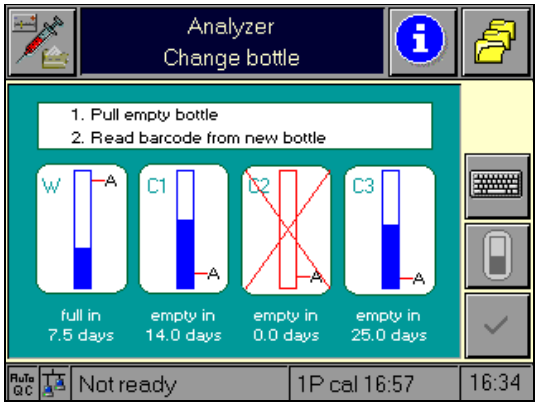


Fig. 17

2.7 Reverse side

See Instructions for Use, chapter 1 "Introduction"!

2.8 Power rating[1] - power supply

Test No.	Voltage V	Frequency Hz	Current A	Power in W	Power in VA	Comments / operating conditions
1	90	50	2.01	145	174	warm-up
2	100	50	1.78	145	175	warm-up
3	240	50	0.78	133	188	warm-up
4	264	50	0.72	137	191	warm-up
5	90	60	2.18	148	196	warm-up
6	100	60	1.95	142	194	warm-up
7	120	60	1.67	138	200	warm-up
8	132	60	1.54	139	203	warm-up
9	240	60	0.97	133	233	warm-up
10	264	60	0.89	131	235	warm-up
11	240	50	0.29	44	70	Standby / normal operating conditi-ons

2.9 Instrument cover

The instrument cover provides mechanical protection for the measuring chamber, pump and valves. The cover is removable, but must remain closed while the unit is in operation.

[1] Taken from the report of VDE: Testing and Certification Institute

2.10 Tubing system

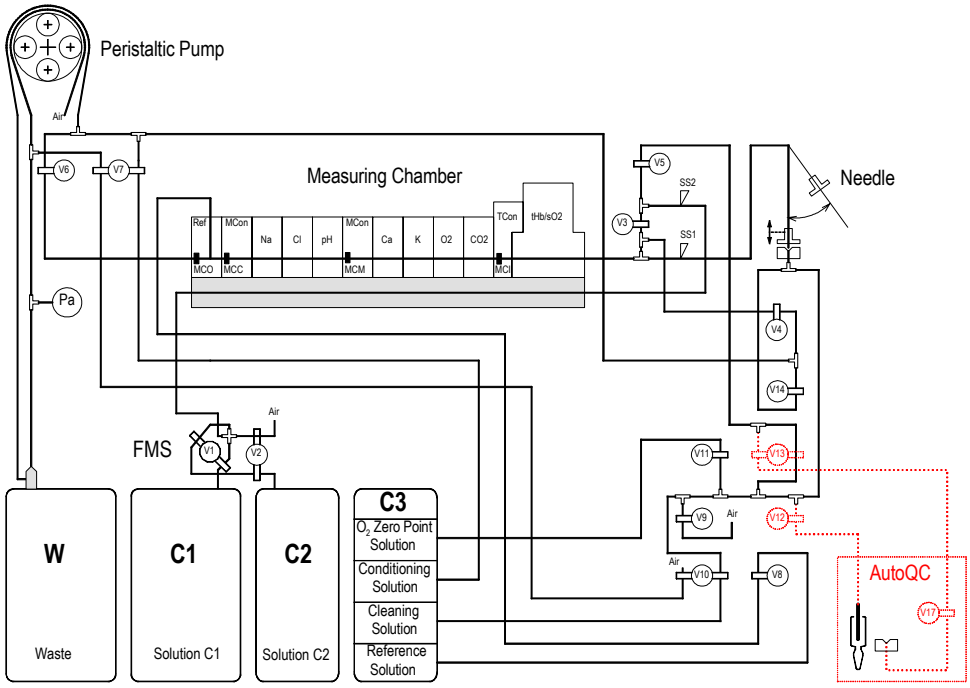


Fig. 18

V1 ..... C1/C2 mixing valve
V2 ..... Air mixing valve
V3 ..... MC wash valve
V4 ..... MC bypass valve
V5 ..... Wash needle
V6 ..... MC out
V7 ..... Conditioner
V8 ..... Reference solution
V9 ..... Ventilation
V10 ..... Cleaning solution
V11 ..... Zero point solution
V14 ..... Bypass

SS1, SS2..... Sample sensors

If the AutoQC module has been installed:

V12 ..... AQC valve
V13 ..... AQC wash valve
V17 ..... AQC wash valve II

3 Operating modes

3.1 Analyzer 3-1

3.1.1 "Ready" screen 3-1

Parameter – depiction and buttons 3-1
Mandatory input 3-2
Password 3-2

3.1.2 System 3-3

Wash and clean 3-4
Tools 3-6
Test 3-13
Calibrations 3-26

3.1.3 Quick access 3-26

3.1.4 QC measurement 3-26

3.2 Setup 3-27

3.2.1 Parameter 3-27

Miscellaneous settings 3-28
Reference / critical ranges 3-31
Correlations 3-32

3.2.2 Times & intervals 3-33

Date and time 3-33
Calibration intervals 3-34
QC times 3-34
Economy mode 3-34
Timeouts 3-38

3.2.3 QC material 3-39

Set ranges 3-39
AutoQC mat setup 3-39

3.2.4 Interfaces 3-40

Network 3-40
ASTM communication 3-42
COM 1 3-42
COM 2 3-44

3.2.5 Displays & reports 3-45

Measuring data 3-46
Parameter: display ranges 3-54
QC 3-54
Calibration 3-54
Patient database 3-54
Instrument data 3-55

3.2.6 Instrument 3-56
Language 3-57
Roche info 3-58
Brightness level 3-59
Speaker 3-59
Automatic patient ID 3-60
Other units 3-60
Clinic info 3-61
Cleaning counter 3-61
AutoQC 3-62
Ext. patient query 3-62
3.2.7 Password 3-63
Security level 3-63
User management 3-63
Group administration 3-64
3.2.8 Service area (password protected) 3-64
3.3 Database 3-65
3.3.1 Patient data 3-65
3.3.2 Measuring data 3-66
3.3.3 Calibration data 3-67
3.3.4 QC data 3-67
3.3.5 Instrument data 3-68
3.3.6 Data export 3-69
3.3.7 Delete data 3-70

3 Operating modes

The Roche OMNI C is a combined bloodgas, electrolyte, and tHb/SO_2 analyzer. It is possible to complete database procedures or to make adjustments simultaneously during measurement or calibration.

The individual, mutually independent operating modes are defined as follows:

a) Analyzer: measuring, QC, system, calibration, quick access
b) Setup: instrument settings
c) Database: contains data on patients, measuring, calibration, QC, and the instrument
d) Info: Roche info, version numbers, fill levels, help, sensor status

3.1 Analyzer

The Analyzer operating mode has a special status among the operating modes.

3.1.1 "Ready" screen

The Ready screen is the central starting point for all operations.

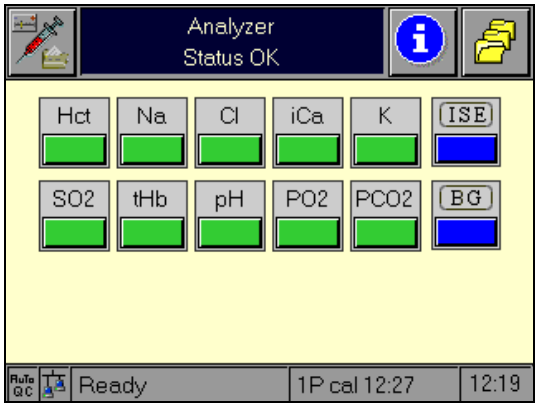


Fig. 1

Parameter – depiction and buttons

For a description of the parameter depiction and buttons, please see **Instructions for Use**, chapter 1, "**Introduction.**"

Mandatory input

Furthermore, the "Ready" screen can be modified by the activation of a "Mandatory input" field. If this function is activated in the "Setup" mode, a measurement can be started only when the entry has been completed.
In the following example, the access code has been defined as a mandatory entry.

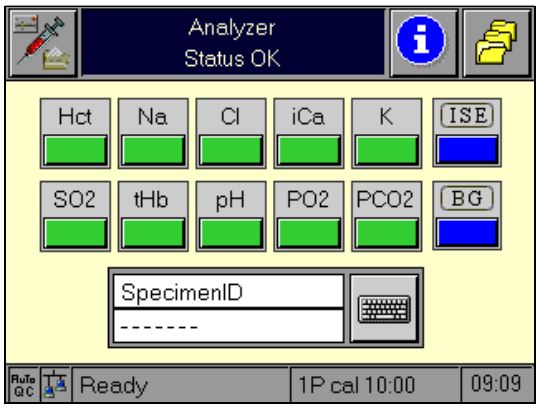


Fig. 2

Password

If the measurement is equipped with password protection, the "Ready" screen is covered by the password window but the parameter section remains visible (parameter information).

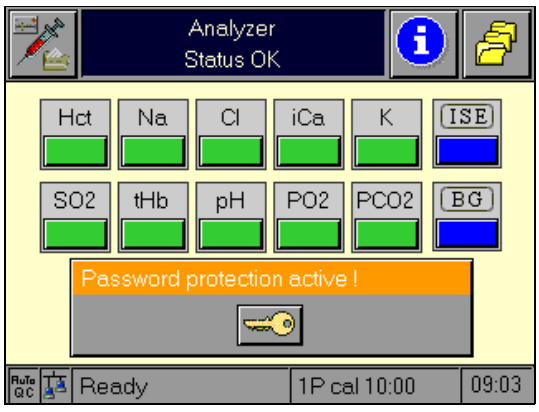


Fig. 3

3.1.2 System

The system section can be reached directly and only from the "Ready" screen.
This occurs by pressing the button.
This button calls up a window with which the following functions may be activated:

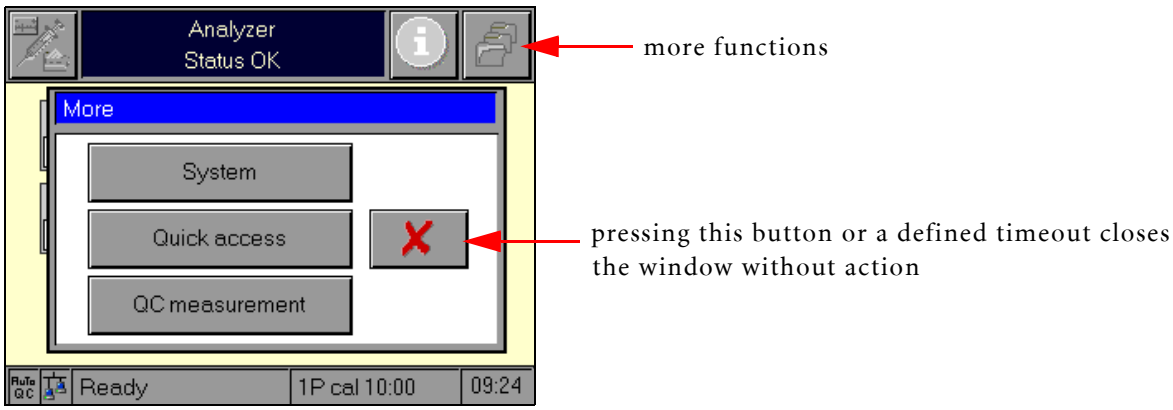


Fig. 4

The following main menus are available:

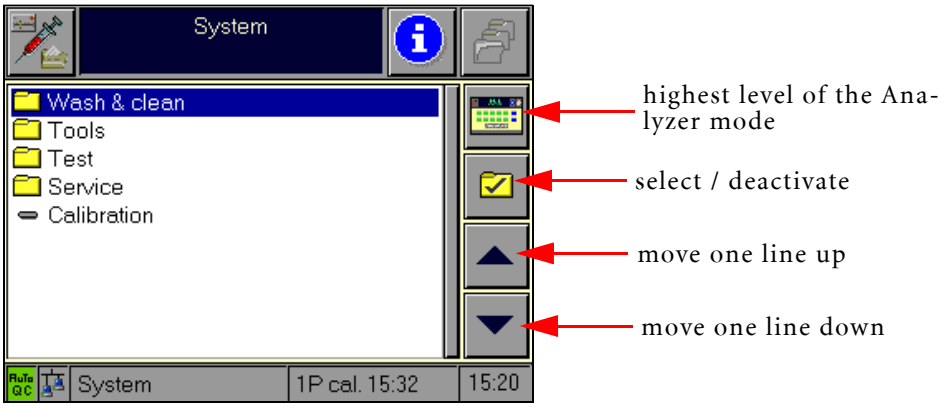


Fig. 5

Wash and clean

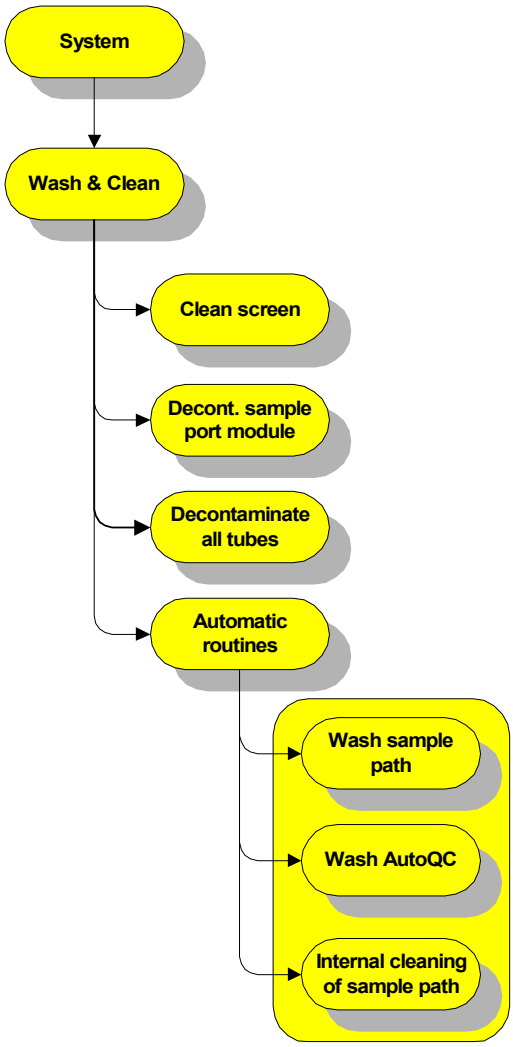


Fig. 6

Clean screen

Upon entry into this function, the screen clears (white) and the touch screen deactivates for 30 seconds. A counter on the screen indicates the remaining number of seconds.
After expiration of the 30 seconds, the next highest level menu appears again. Please see chapter "Maintenance" in the Instructions for Use for instructions on this cleaning procedure.

Decontaminate sample port module

This function assists in the decontamination of the sample port module, which consists of flap, needle, filling port holder, filling port, and wash plate.

Please see chapter "Maintenance" in the Instructions for Use for instructions on this cleaning procedure.

Decontaminate all tubes

Follow the instructions on the screen. Confirm every step with !
The shutdown kit gives instructions on decontaminating all tubing.

For a description, please see Instructions for Use, chapter 6, "Maintenance", section "Decontamination – Tubing paths."

Automatic routines

Wash sample path

This function washes out the sample path. It is not possible to interrupt this routine.

Wash AutoQC (option)

This function washes the optional AutoQC module if it is installed. It is possible to interrupt this sequence.

Internal cleaning of sample path

This function cleans the sample path. It is not possible to interrupt this sequence.

Tools

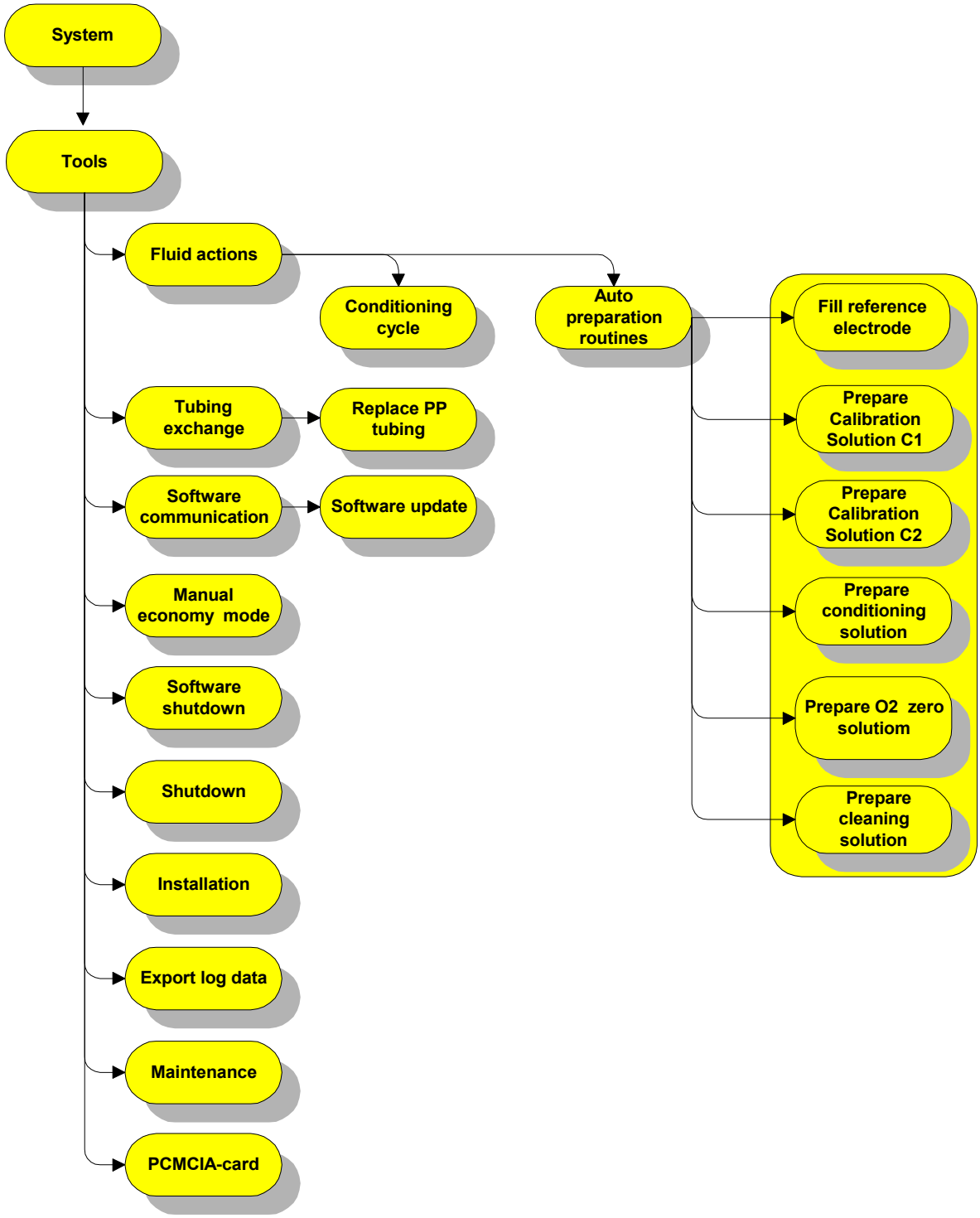

System
Tools
Fluid actions
Conditioning cycle
Auto preparation routines
Fill reference electrode
Prepare Calibration Solution C1
Prepare Calibration Solution C2
Prepare conditioning solution
Prepare O2 zero solutiom
Prepare cleaning solution
Tubing exchange
Replace PP tubing
Software communication
Software update
Manual economy mode
Software shutdown
Shutdown
Installation
Export log data
Maintenance
PCMCIA-card

Fig. 7

Fluid actions

Conditioning cycle

This function conditions the unit. It starts a sequence as with other automatic suction routines. The sequence may not be interrupted and displays a message in the event of a fault.

Auto preparation routines

Fill reference electrode

This function suctions the reference solution to the reference sensor. The sequence may not be interrupted and displays a message in the event of a fault.

Prepare Calibration Solution C1

This function provides upward suction of the C1 calibration solution 1. The sequence may not be interrupted and displays a message in the event of a fault.

Prepare Calibration Solution C2

This function provides upward suction of the C2 calibration solution 2. The sequence may not be interrupted and displays a message in the event of a fault.

Prepare conditioning solution

This function provides upward suction of the conditioning solution. The sequence may not be interrupted and displays a message in the event of a fault.

Prepare *PO_2 zero solution*

This function provides upward suction of the PO_2 zero solution. The sequence may not be interrupted and displays a message in the event of a fault.

Prepare cleaning solution

This function provides upward suction of the cleaning solution. The sequence may not be interrupted and displays a message in the event of a fault.

Tubing exchange

PP tubing exchange

This function is used to perform the exchange of the peristaltic pump tubing.

Software communication

Software update

Use this function to load a new program. The required parameters may also be entered. The following parameters are currently available:

Source: FTP, PCMCIA

Update file: update information file

Source path: path to the location of the update file

Host address: IP address of the remote computer if FTP was selected as the source

Start the execution with the button.

Manual economy mode

Use this function to manually activate a pause mode if you do not intend to use the Roche OMNI C for an extended period of time.

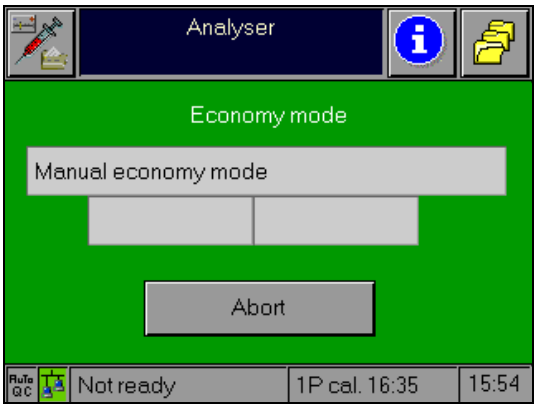


Fig. 8

The units uses smaller quantities of solutions during this time. A system maintenance process ensures that the electrodes remain optimally conditioned, however.

Software shutdown

This function brings the instrument to shutdown status.

It is necessary to follow the proper shutdown procedure because a sudden shutdown can lead to the loss of data!

A message appears on the screen that instructs the user to switch off or restart the instrument.

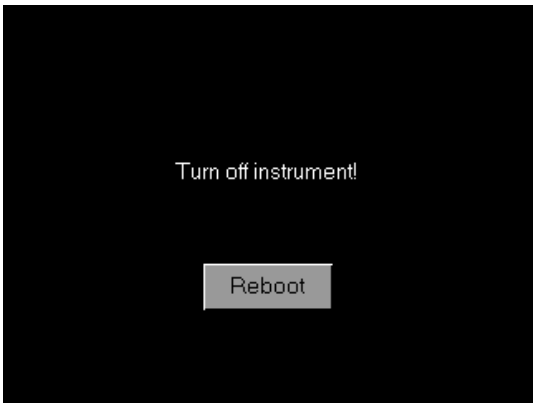


Fig. 9

Shutdown

This function enables program-supported shutdown of the instrument.

Each of the actions that should be performed are listed in the listbox as the final entry. Confirm the manually completed actions.

If any of the actions are to be performed by the instrument, this will be indicated by the blocking of the confirmation button and activation of the "Start action" button. The next step to be performed will be automatically entered into the listbox as the final line. Following completion of instrument actions, the status "OK" or "not OK" is displayed at the end of each line.

For information on the shutdown procedure, please see chapter 1 "**Introduction**", section "**Shutdown**" in the Instructions for Use!

TIP: *After successfully shutting down the instrument, it will be in the "System stop" mode (shut down). This can be reversed only by a renewed startup procedure.*

Installation

This routine enables program-supported startup of an instrument. Each of the actions that should be performed are listed in the listbox as the final entry. Confirm the manually completed actions.

If any of the actions are to be performed by the instrument, this will be indicated by the blocking of the confirmation button and activation of the "Start action" button. The next step to be performed will be automatically entered into the listbox as the final line. Following completion of instrument actions, the status "OK" or "not OK" is displayed at the end of each line.

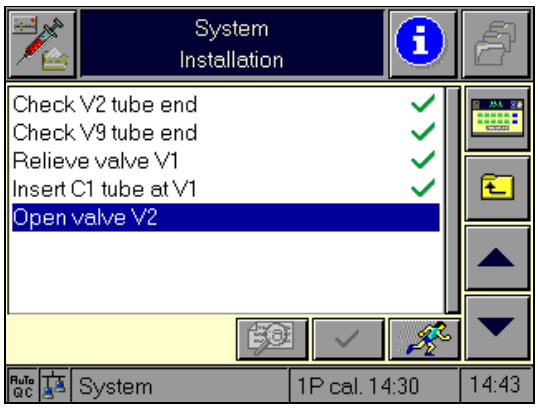


Fig. 10

For information on the startup procedure, please see chapter 1 "**Introduction**", section "**Installation**" in the Instructions for Use!

TIP: *If an error appears following the start of the action "Begin installation routine" (final step of installation), a system stop is displayed but the instrument is regarded as having been brought into operation.*

Export log data

You can use this function to export log data.

TIP: *Selection of all or single log data is possible.*

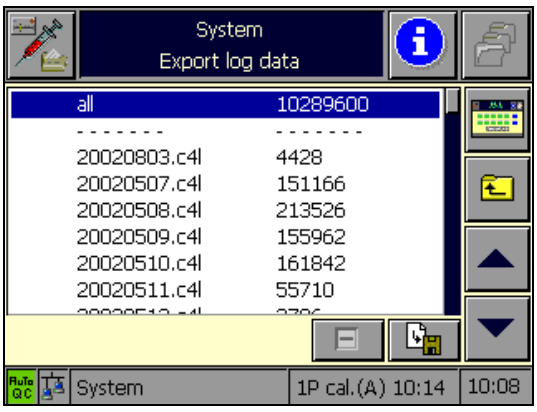


Fig. 11

Use the "line up/down" buttons to select the log data. Then press the key and select where you wish to store the log files.

Only available destinations, such as FTP and PCMCIA, are indicated. Confirm here, all log files are copied. With the PCMCIA card, it is additionally checked whether enough memory is available.

The log files are copied to a fixed "Export" path with the serial number at the front. With the PCMCIA card, an "Export" directory is automatically created, with an FTP transfer, it must already be available.

If log files are available, they can be deleted using the button.
If no log file is available, a corresponding error message is issued in the file list and the and buttons are deactivated.

Maintenance

Use this function to call up an overview of all maintenance entries and their status.

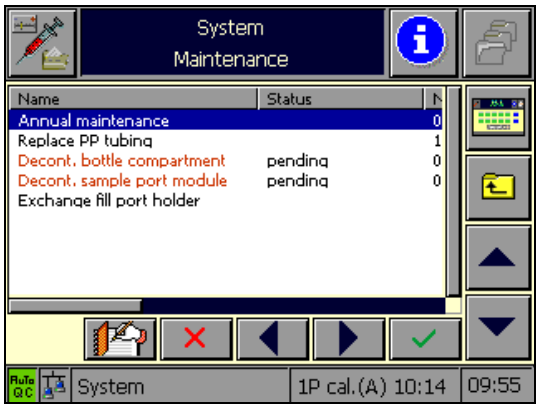


Fig. 12

The following maintenance is entered by default and can be neither deactivated nor renamed:

- Annual maintenance
- PP tubing exchange
- Decontaminate bottle compartment
- Decontaminate sample port module
- Decontaminate screen
- Exchange fill port holder

If a maintenance is planned, it is displayed in "red" in the list.
Use to mark the maintenance as performed. The next cycle time is calculated.

Use to enter the maintenance as "skipped" in the device database.

Use to create a separate entry that is saved in the device database.

PCMCIA card

Use this function to create a defined PCMCIA card.

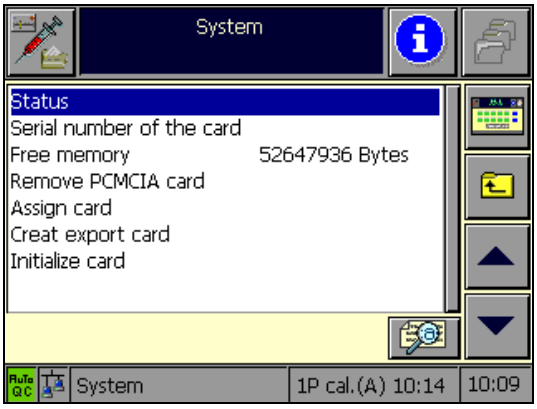


Fig. 13

Status: The current status of the PCMCIA card is displayed. The properties (application purpose) of the card are marked with a green check mark.

Use the button to change the properties of the card.

TIP: If a card is not assigned, no setting can be performed.

Serial number of the card:	The serial number of the PCMCIA card is displayed.
Free memory:	Call up information about the assignment status of the card.
Remove PCMCIA card:	Use this function to remove the card.

Remove the card only by using the "Remove PCMCIA card" menu item, since a sudden removal can lead to data loss!

Assign card:	The card used is assigned to the device.
Create export card:	Create an export card on which database files and log files can not be stored.
Initialize card:	Delete all data on the card.

Test

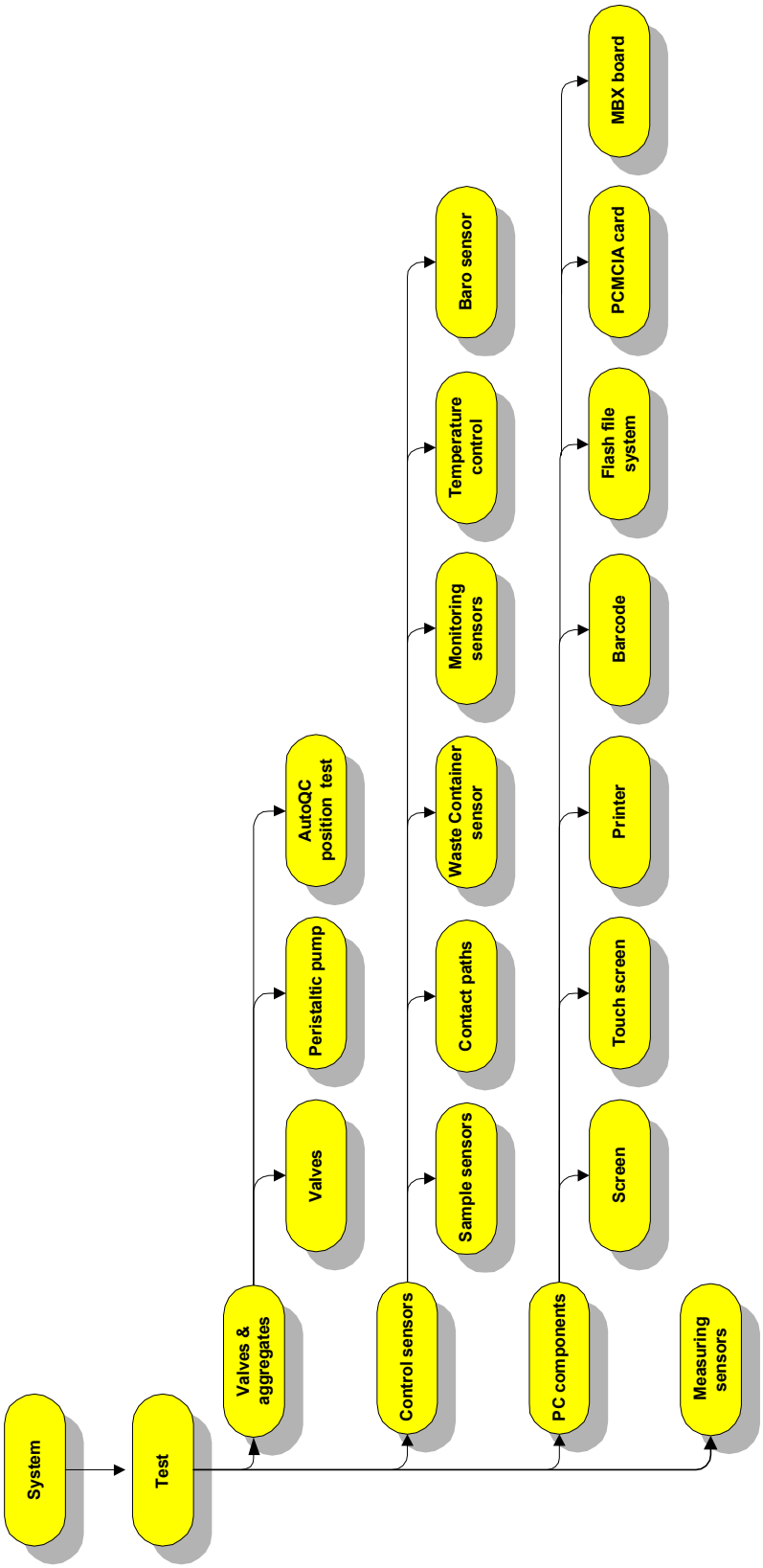

System
Test
Valves & aggregates
Control sensors
PC components
Measuring sensors
Valves
Peristaltic pump
AutoQC position test
Sample sensors
Contact paths
Waste Container sensor
Monitoring sensors
Temperature control
Baro sensor
Screen
Touch screen
Printer
Barcode
Flash file system
PCMCIA card
MBX board

Fig. 14

Valves and aggregates

Valves

This test checks the switching function of all valves. To perform a check, a single valve may be switched or 10 separate switches (5 times open/close or close/open) may be performed automatically.

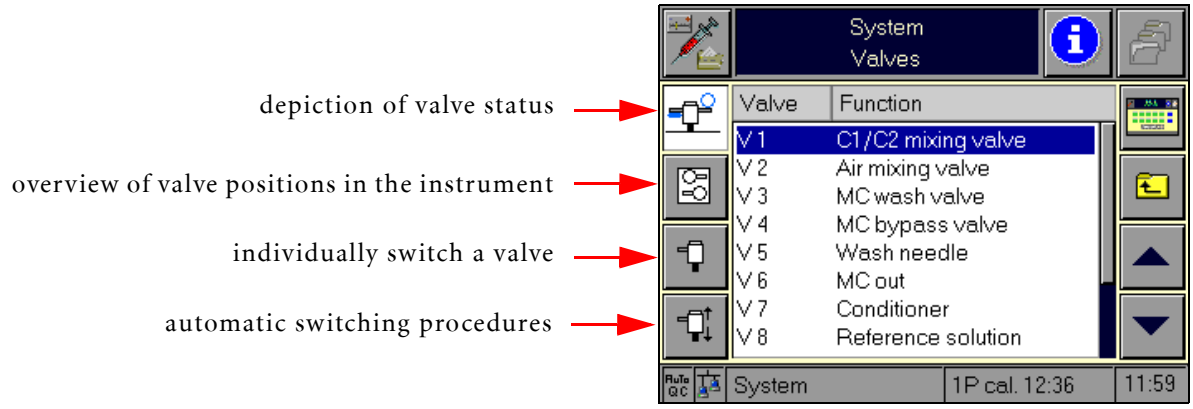


Fig. 15

In addition, the status of each valve is displayed schematically (for example: V1).

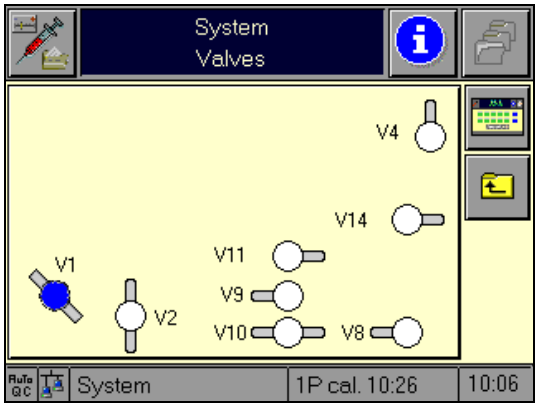


Fig. 16

Peristaltic pump

This test checks the peristaltic pump in four defined speeds.

Only suction is possible because reverse rotation of the pump would remove fluid from the W waste container!

In addition, the following is displayed:

- pump volume in µl per revolution
- the FMS volumes in µl

Service technicians and certain users are able to start a calibration sequence for the pump. They are then also able to re-establish the FMS volumes and save these as new settings.

Press the key and follow the instructions on the screen.

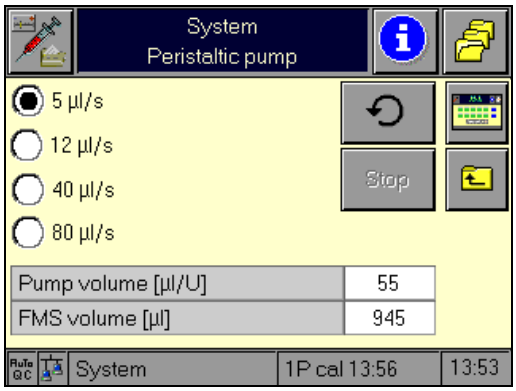


Fig. 17

AutoQC position test

This function tests the positions of the ampoule block.

The following positions are possible:

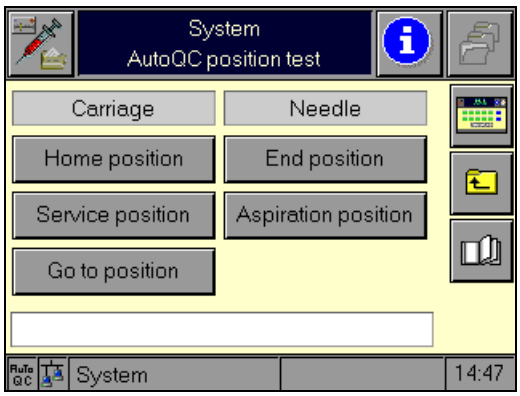


Fig. 18

Position:

"Home position": the needle is positioned over the wash port

"Service position": *NOTE: remove the ampoule block before going to the service position.*

The carriage moves to position 106.

"Go to position": goes to any ampoule position from 1 to 120.

Needle:

"End position":the carriage with the needle moves upwards to the end position.

"Aspiration position": the carriage with the needle moves downwards to the aspiration position.

CAUTION: danger of injury from moving parts!

Control sensors

Sample sensors

This test completes a check of the optical sample sensors 1 and 2.
The following is also displayed:

- calibration value of the sensor
- actual measurement value in mV
- actual measurement value in % based on the calibration value
- evaluation of the actual measurement value or notification that plausibility test is not acceptable

Service technicians and certain users are able to start a calibration sequence for the sample sensors. This sequence determines the calibration value for the specific sensor and adopts this as the new setting.

Press the button and follow the instructions on the screen.

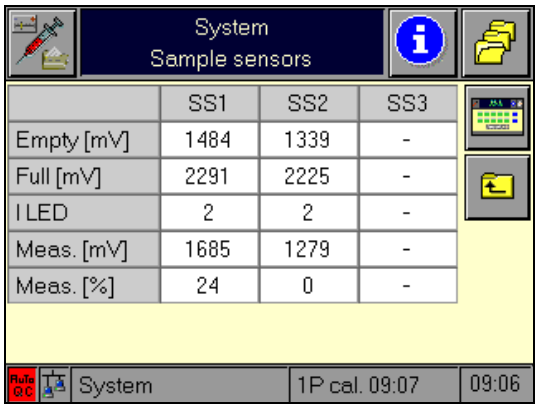


Fig. 19

Contact paths

The actual entered conductivity values are displayed (in mV) for the specified contact paths with the fluid available in the sample channel.

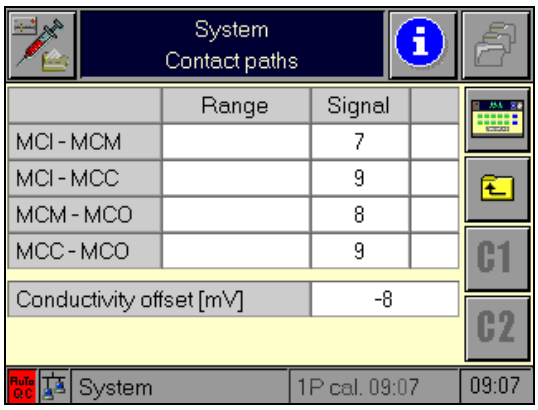


Fig. 20

Waste container sensor

Display of the actual values for the waste water sensor.

- actual value: signal in mV
- slope in mV/mbar
- zero point in mV (determined in advance during the measurement)
- fill level in %
- fill level in mm (last measured value, manually or by a system calibration)

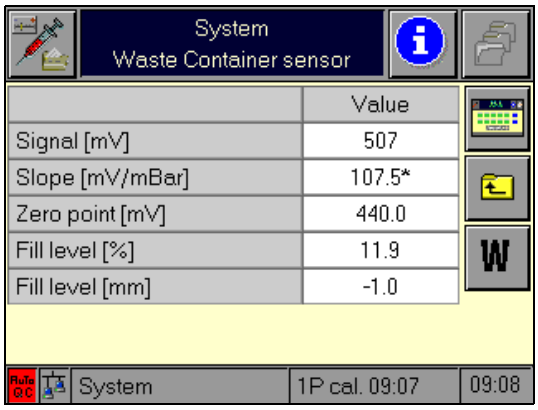


Fig. 21

Use the W button to determine the current fill level in mm (see Fig. 20).

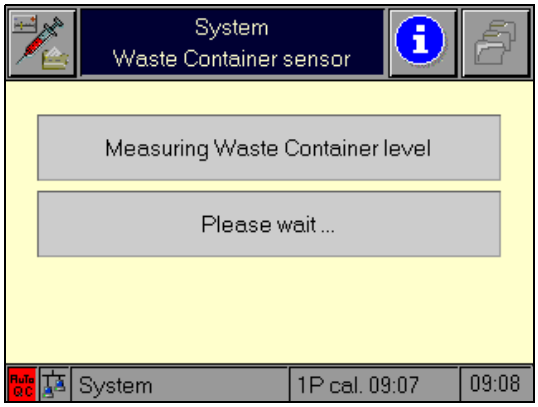


Fig. 22

Monitoring sensors

This test window displays the status of all monitoring sensors.

These are:

- Sample port module
  status: closed, syringe position, capillary position
- MC cover
  status: open, closed
- Bottle compartment

status: open, closed

- C3 docking mechanism
  status: open, closed
- W waste container
  status: open, closed
- AutoQC cover
  status: open, closed

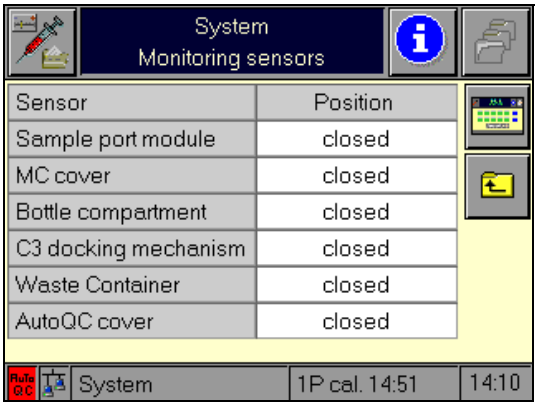
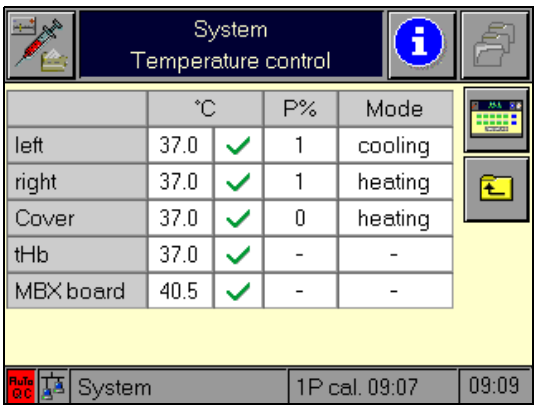
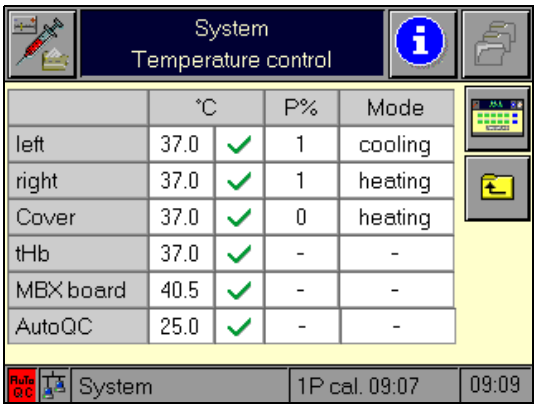


Fig. 23

Temperature control

Actual temperature display.





with AutoQC

Fig. 24

Limit values are established for the following boards:

MBX board: 1 - 55 °C

Baro sensor

Display of the actual values for the baro sensor.

These are:

- actual value in mV
- calibration point in mV
- slope in mV/bar
- calculated air pressure in the unit according to adjustments

Service technicians and certain users are able to start a calibration sequence for the baro sensor. This sequence determines the calibration value for the baro sensor and adopts this as the new setting.

Press the button and follow the instructions on the screen.

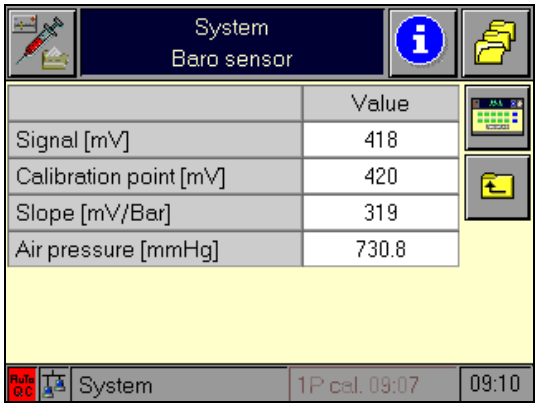


Fig. 25

PC components

Screen

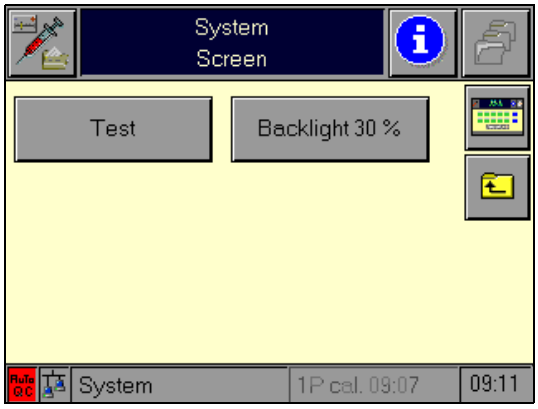


Fig. 26

The "Test" function helps to check the functionality of the screen.
These are:

- checking for failure of individual picture elements
- checking for failure of colours

- checking the illumination lamps (on/off/?)

The following test procedure will be executed:

1. Black screen (for 5 seconds)
2. White screen (for 5 seconds)
3. Display of complete colour palette (for up to 2 minutes) (see Fig. 27).

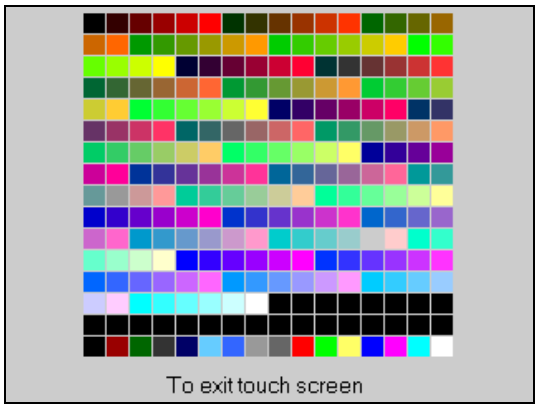


Fig. 27

Use the "Lamps to 30%" function to switch the illumination lamps from 100% to 30% power. The lamps are set back to 100% when exiting this function (see Fig. 26).

Touch screen

This test function checks the functionality of the touch screen. It is also possible to adjust the offsetting of the touch screen in relation to the display.

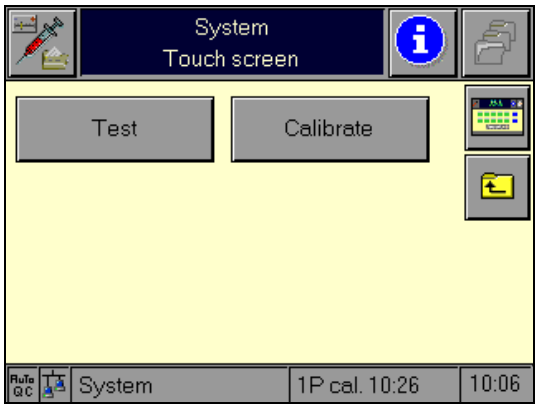


Fig. 28

By pressing the "Test" button, you can check if the entire (black) area is active as a touch-sensitive surface (see Fig. 29).

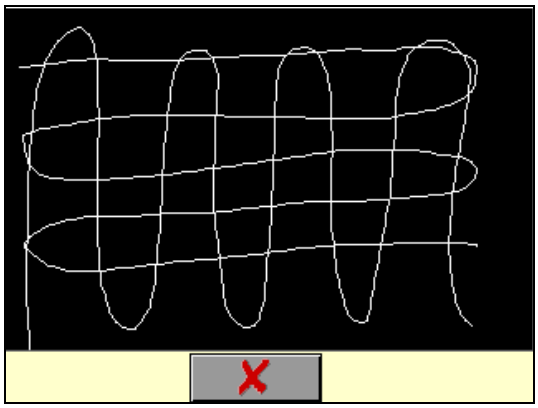


Fig. 29

By pressing the "Calibrate" button, you can use a pencil or other pointed object (but which is not too hard, to avoid scratching the surface) to touch the white points in the upper left and lower right corners.

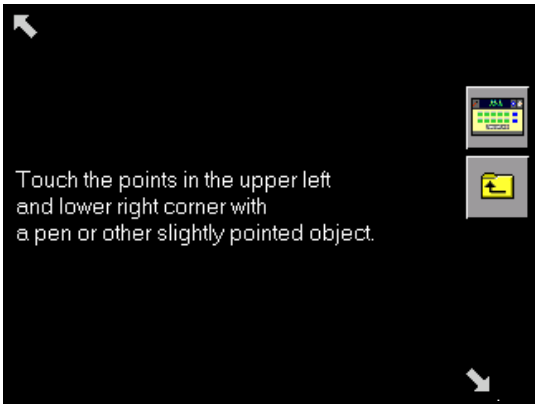


Fig. 30

After release, the instrument will accept the exact position. From this time on, the instrument will use the touched points to calculate the offset between the displayed pixels and the touch screen. After a point has been accepted, the arrow disappears. The point itself remains visible and active (pressing the position again re-establishes the point).

After leaving the window, the new correction values take effect.

Printer

The printer test screen shows the current status of the printer. If there is a print job in the printer queue when switching into the printer window, all buttons, with the exception of the reset button, are made inactive. As soon as the printer is ready again, the additional functions are made active and the printer queue blocked.

The additional functions (for example: Paper feed) can be used only when the printer status is "Ready". Pressing the "Reset" button resets the printer before the status is redetermined.

IMPORTANT: The printer queue remains blocked as long as this screen is open, because this is where the printer is accessed. The printer queue is enabled as soon as you leave this screen.

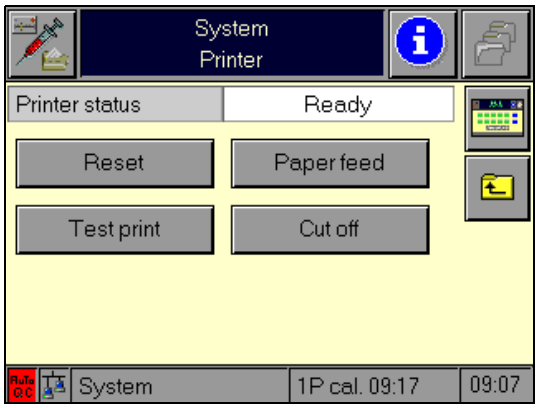


Fig. 31

Test print: starts a test print with all available symbols.

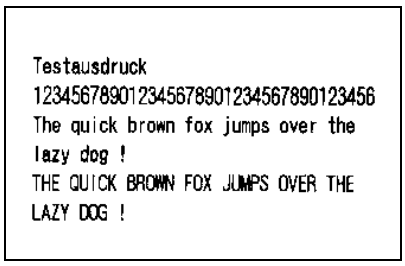


Fig. 32

Barcode

Test functions check the functionality of the interface. A variety of barcodes (including barcodes not belonging to the unit) can be read in.

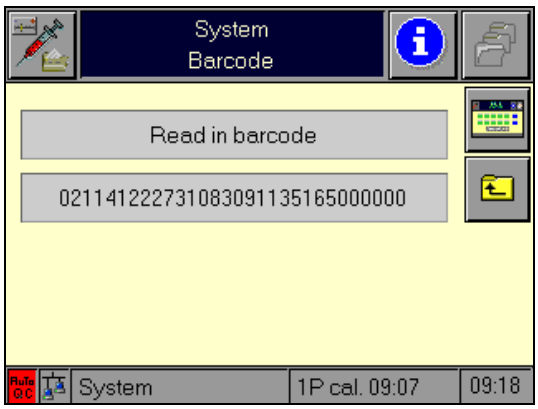


Fig. 33

Flash file system

This test function can check the status of a flash file system.

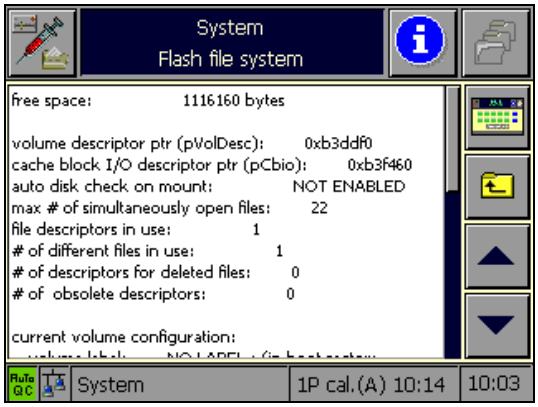

System
Flash file system
free space: 1116160 bytes
volume descriptor ptr (pVolDesc): 0xb3ddf0
cache block I/O descriptor ptr (pCbio): 0xb3f460
auto disk check on mount: NOT ENABLED
max # of simultaneously open files: 22
file descriptors in use: 1
# of different files in use: 1
# of descriptors for deleted files: 0
# of obsolete descriptors: 0
current volume configuration:
System
1P cal.(A) 10:14
10:03

Fig. 34

PCMCIA card

These test functions can check the PCMCIA interface or check if the inserted card is recognized.

Press:

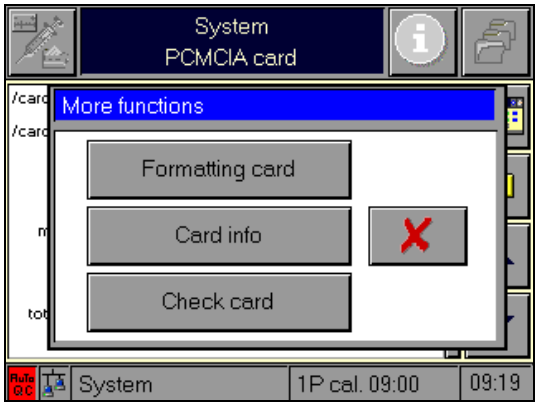


Fig. 35

The following additional functions are also available:

- Formatting card
- Card info
- Check card

MBX board

This test function provides you with information about the main board and the IO board.

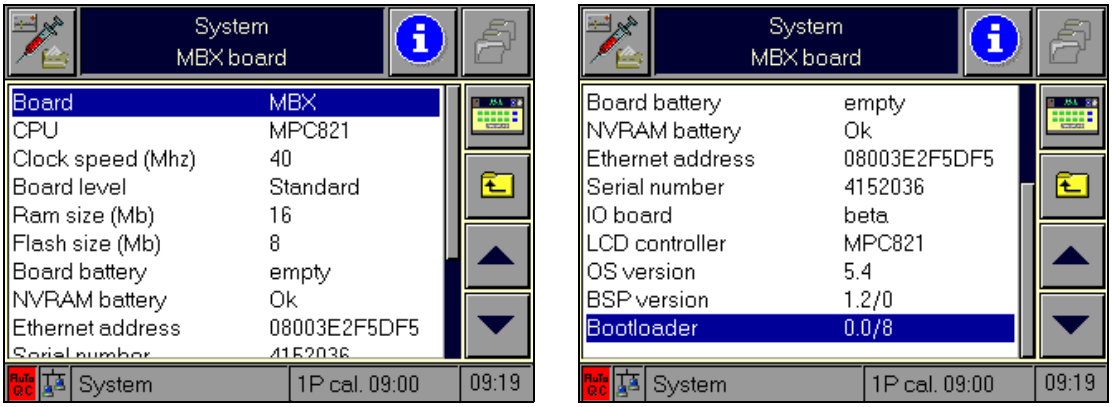


Fig. 36

The following data are provided:

Board type	MBX
CPU	MPC821 / MPC860
Clock frequency	40 / 50 Mhz
Board level	standard or entry level
Size of the main memory in MB	
Size of the flash memory in MB	
Status of the board battery	OK / empty
Status of NVRam battery	OK / empty
Ethernet address	instrument-dependent
Serial number of the MBX board	instrument-dependent
IO board version	beta / series 0 /...
LCD controller	MPC821 on chip / Epson SED1375
Operating system version	
Board support package version	
Bootloader version	

Measuring sensors

Display of the actual electrode values. If the contents of the measuring chamber have not changed since entering "system" (e.g. by drawing fluids), signal evaluation.

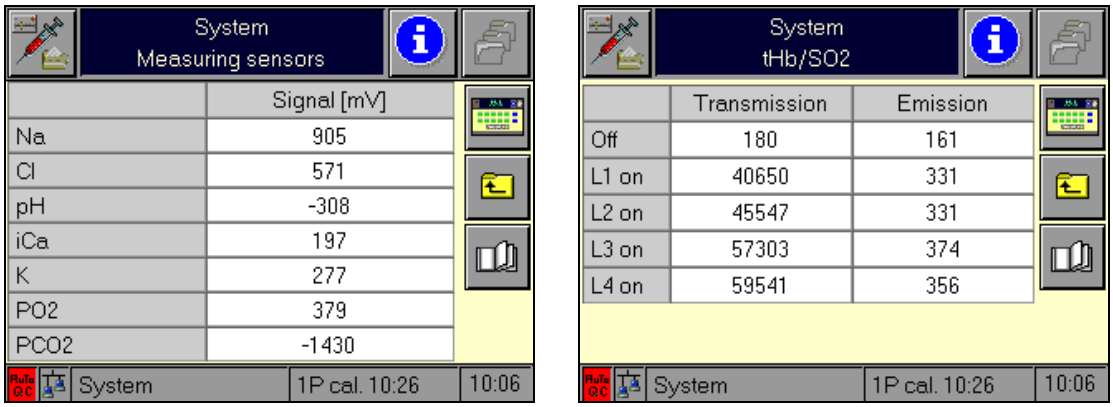


Fig. 37

Display of the four laser diodes' actual values for the transmitted light and diffused light channels.

Calibrations

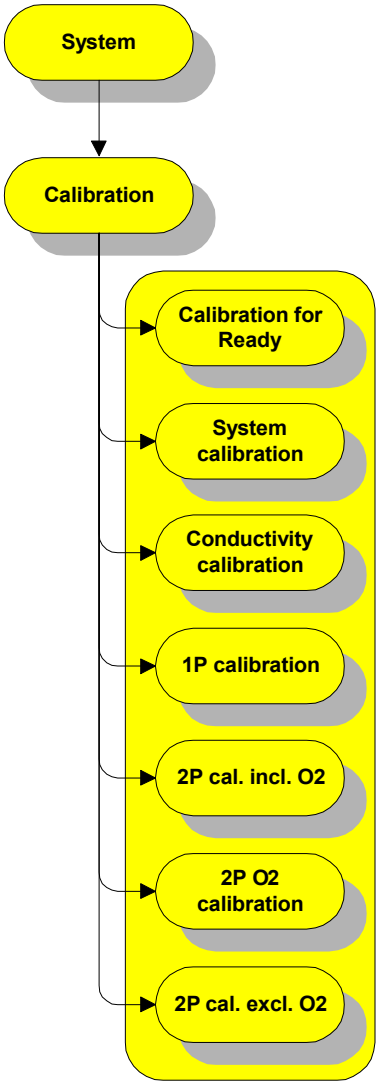


Fig. 38

Use this function to manually start the calibrations.

3.1.3 Quick access

See Instructions for Use, chapter 8 "**Operating modes**", section "**Analyzer – Additional functions.**"

3.1.4 QC measurement

This function starts a QC measurement.

Please see Instructions for Use, chapter 5 "**Quality control**" for the procedures of this QC measurement!

3.2 Setup

Use this function to make the following settings:

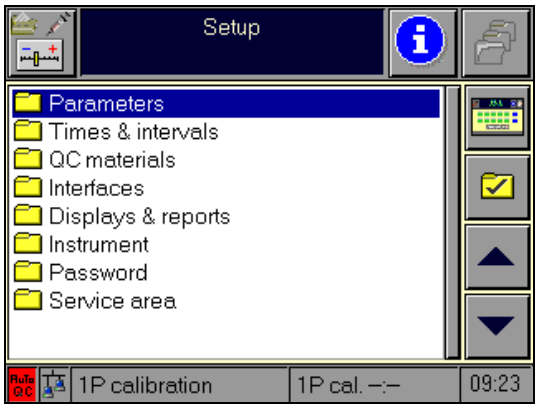


Fig. 39

3.2.1 Parameter

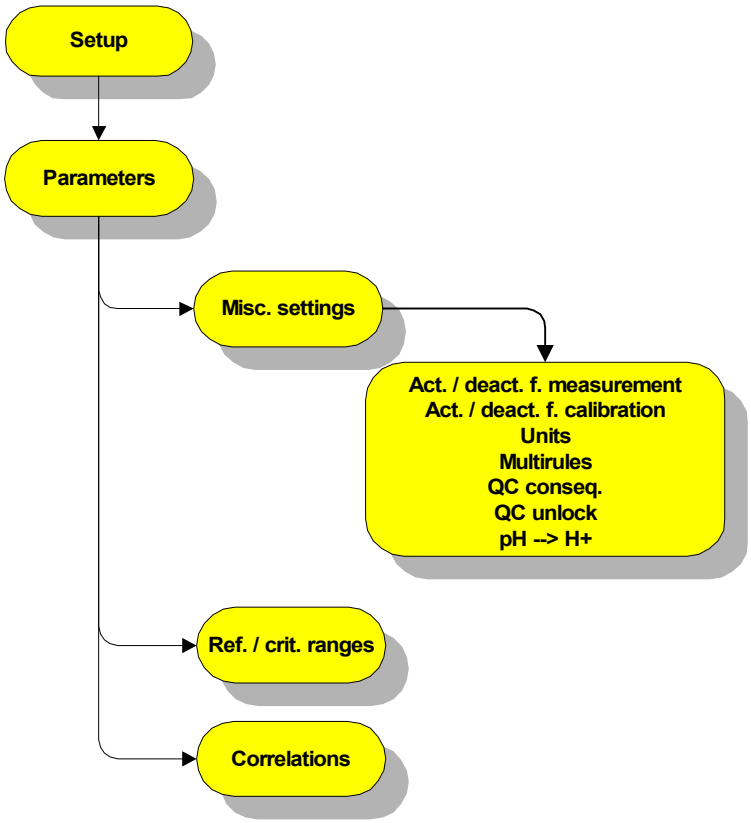


Fig. 40

Miscellaneous settings

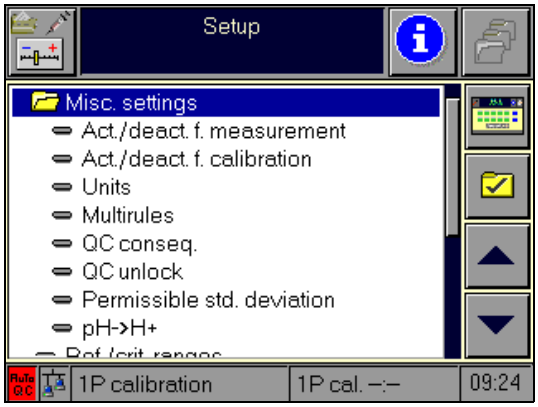


Fig. 41

Activate / deactivate for measurement

Use this function to activate or deactivate measurement parameters (please see Instructions for Use, chapter 1 "Introduction", for the depiction of the parameters).

Activated parameters are displayed green in the "Ready" screen, deactivated parameters are gray. The parameters are calibrated regardless of the setting and, if they are shown in gray, can be switched on (in the "Ready" screen) for a measurement.

Activate / deactivate for calibration

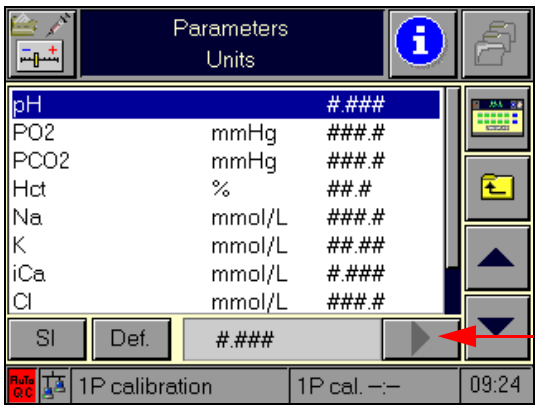
The parameter(s) are not calibrated and cannot be measured.

TIP: Be certain to insert a dummy in place of the deactivated electrode(s)!

The deactivated parameter's symbol is struck out with gray and red and cannot be activated in the "Ready" screen.

Units

Use this function to define the format and the unit for each individual parameter.



select format and unit

Fig. 42

Using the "line up / line down" buttons , you can now select the parameter for which you want to set the format and unit.

Pressing the "SI" button converts all parameters to SI units.

Pressing the "Def." button establishes predefined formats and units.

The following formats and units can be defined:

Measured values

Designation	Format & unit 1 [Def.]	Format & unit 2 [SI]	Format & unit 3
pH	x.xxx [-]		
H^+	xxx.x nmol/L		
PO_2	xxx.x mmHg	xx.xx kPa	
PCO_2	xxx.x mmHg	xx.xx kPa	
Hct	xx.x %	xxx.x [-]	
Na^+	xxx.x mmol/L		
K^+	xx.xx mmol/L	xxx.x mmol/L	
Ca^{2+}	x.xxx mmol/L	x.xxx mg/dL	
Cl^-	xxx.x mmol/L		
tHb(I)	xx.x g/dL	xxx.x g/L	xx.x mmol/L
SO_2 (I)	xxx.x %	xxx.x %	

Multirules

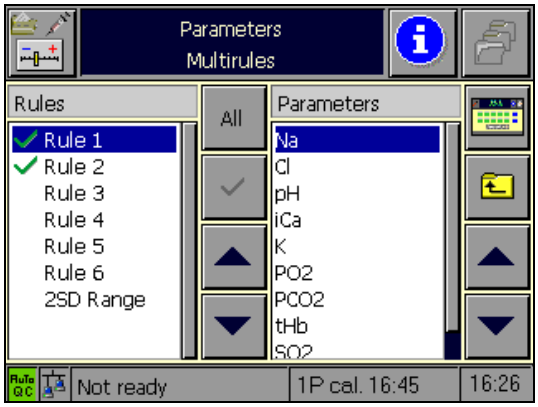


Fig. 43

Use this function to assign to each parameter one or several rules (rules 1-6) or a range examination (2SD range).

For a precise description, please see the operating manual, chapter 5 "**Quality control**"!

QC consequences

Use this function to assign to each individual parameter one of these QC consequences.

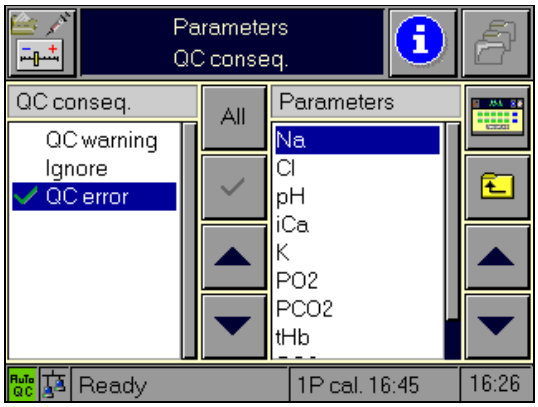


Fig. 44

For a precise description, please see the operating manual, chapter 5 "**Quality control**"!

QC unlock

This overview displays all parameters that are blocked by QC measurements. Pressing the button lifts this block individually for each blocked parameter.
Pressing the "All" key lifts the block for all listed parameters.

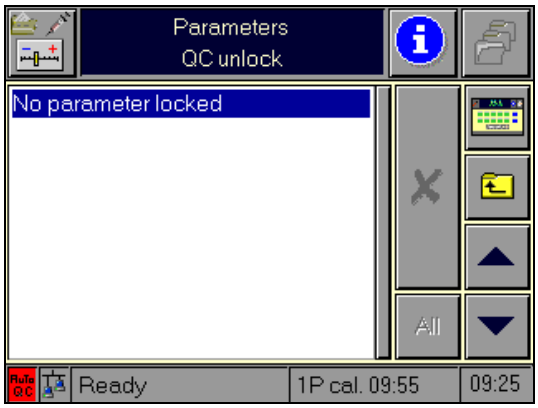


Fig. 45

pH -> H+

Use this function to convert from pH to H^+. Upon activation, H^+ is displayed and converted instead of pH.

Default parameter: pH

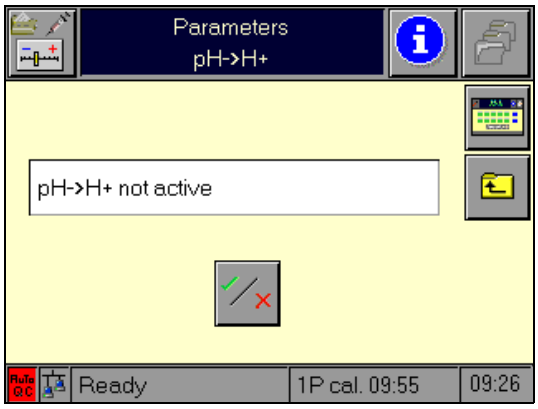


Fig. 46

Reference / critical ranges

In this menu you can enter the upper and lower limits of the reference and critical measurement ranges.

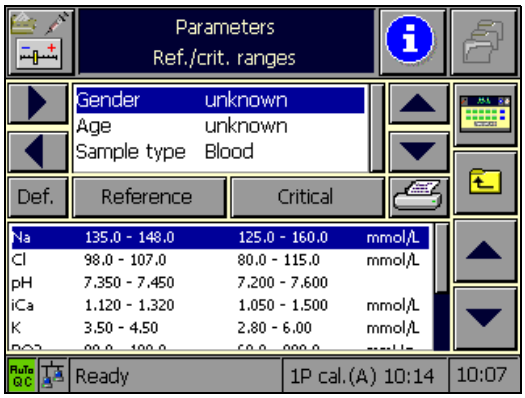


Fig. 47

Use the "line up/down" buttons to select the gender, age and sample type.

Press – the following choices are available for the gender, age and sample type:

Gender: unknown, male, female

Age: unknown, fetus, 2 days - 1 year, older than 1 year

Sample type: blood, serum/plasma, aqueous solution, acetate, bicarbonate

"Def.": the default values will be loaded.

"Reference": enter the upper and lower limits of the reference range.

"Critical": enter the upper and lower limits of the critical measurement range.

Use this function to select the range to be displayed: "Reference", "Critical" or "No display".

Correlations

By pressing the "Offset" button, you can enter an addition or subtraction value for the selected parameter. This value corrects the measurement value.
By pressing the "Slope" button, you can enter a multiplicative factor for the selected parameter to correct the measurement value.

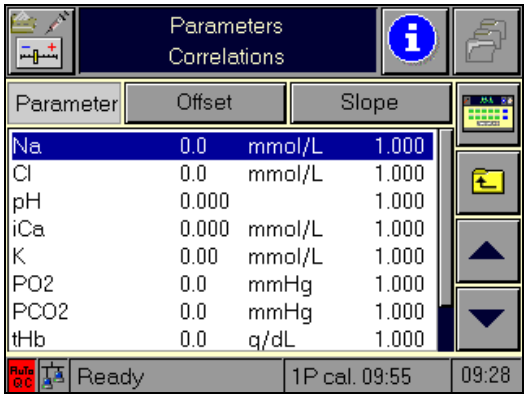


Fig. 48

3.2.2 Times & intervals

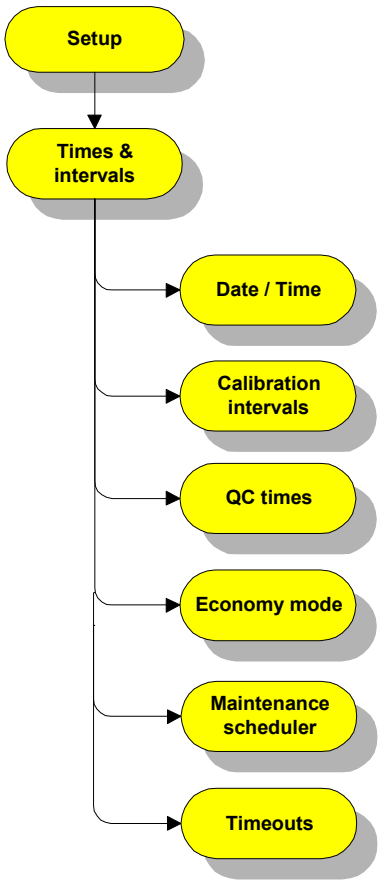


Fig. 49

Date and time

Use the numerical keypad to enter the date and time.
The time and date display formats can also be set with this function.

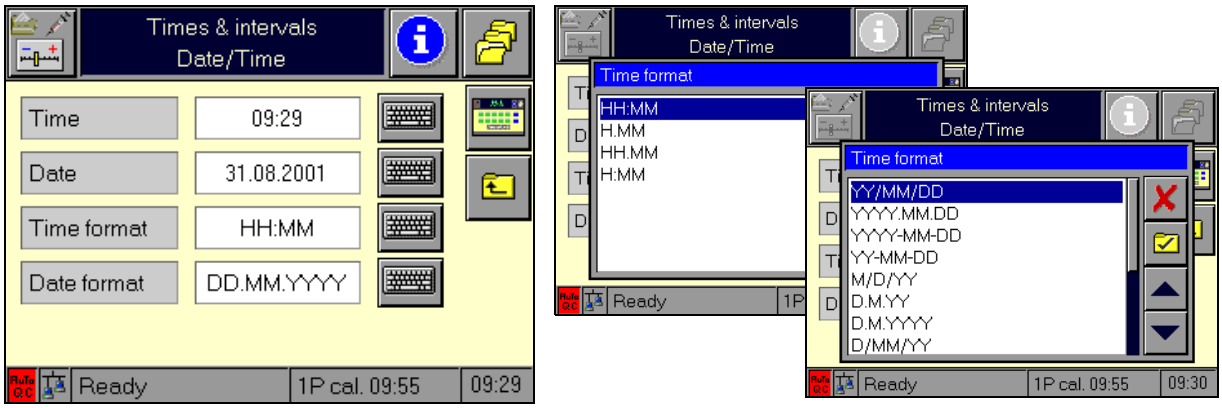


Fig. 50

Calibration intervals

Use this function to enter the automatic calibration times for system calibration, 2P calibration and 1P calibration, as well as the start time (when the system calibration should be performed).

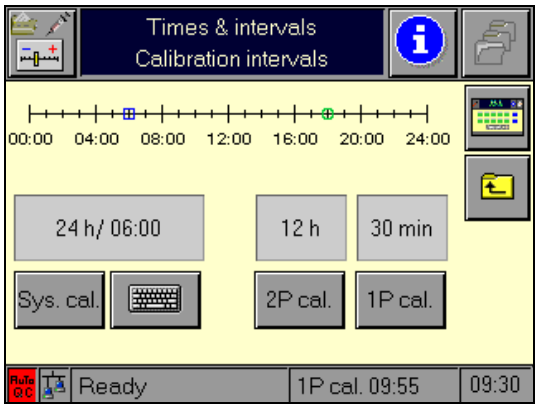


Fig. 51

Intervals:

Sys.cal:	8, 12 and 24 hours
2P cal:	4, 6, 8 and 12 hours
1P cal:	0 and 60 minutes

The time scale uses markers to show the selected interval for the 2P calibration and the start time for the system calibration.
The green markers indicate the start time of the 2P calibration, based on the start time of the system calibration (blue marker).

QC times

See "Instructions for Use", chapter 5 "Quality Control"!

Economy mode

Use this function to select the start time(s) and end time(s) for the Economy mode.

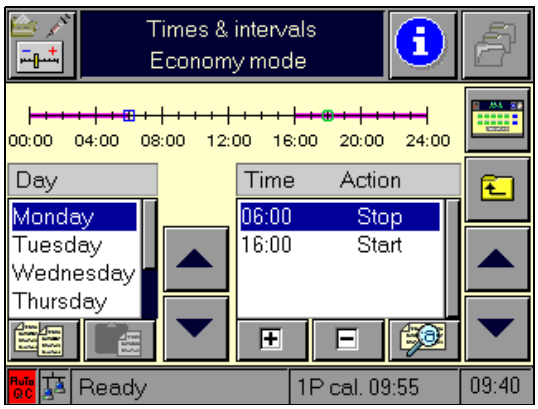


Fig. 52

Select the day from the "Day of Week" list on which the Economy mode should be performed.

You can edit the attributes of the time entries.

Add a new time entry (you can remove it again with).

The following screen appears:

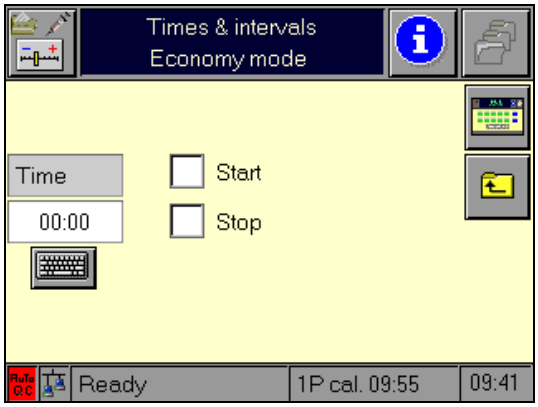


Fig. 53

Enter the starting time or end time.

Mark the appropriate box ("Start" / "Stop").

Press .

Copying a time entry

Select a day of the week and a time entry and press – the selected start and end time(s) of this weekday will be copied.

Select another day of the week and press – the copied time entry will be entered for the new weekday.

These entries can be transferred to as many other weekdays as required.

Maintenance scheduler

This function can be used to add further maintenance to the list.

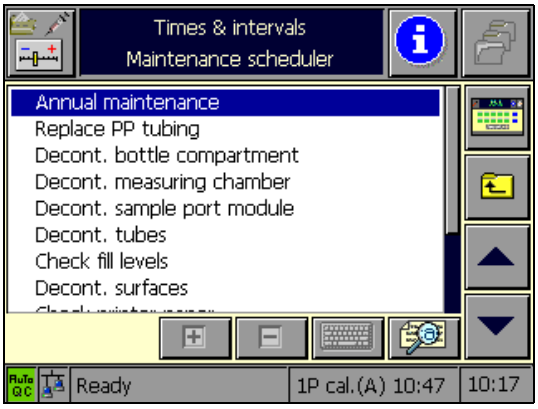


Fig. 54

The following maintenance is entered by default and can be neither deleted nor renamed:

- Annual maintenance
- PP tubing exchange
- Decontaminate bottle compartment
- Decontaminate measuring chamber
- Decontaminate sample port module
- Decontaminate tubing paths
- Fill level check
- Decontaminate surfaces
- Printer paper check
- Decontaminate screen
- Exchange fill port holder

TIP: The attributes of standard maintenance can only be edited to a limited extent.

Use the button to add a new maintenance entry (use to remove it again).

TIP: It is not possible to add a new maintenance entry between two standards services.

Use to enter a name.

Switch to the following view by pressing the button:

Fig. 55

Use to define the properties of the maintenance.

Name:	Enter the name of the maintenance.
Cycle:	Select the maintenance cycle. Available maintenance cycles are: Never, Once, Daily, Weekly, Monthly, Every 3 months, Every 6 months, Annually.
	TIP: Use the maintenance cycle "Never" for time-independent maintenance (e.g. if a maintenance is dependent upon the number of samples).
Time:	Enter the start time of the maintenance. This setting can not be defined if no cycle is set.
Date:	Enter the date that forms the basis for the cycle. This setting can not be defined if no cycle is set.
Sample counter:	Enter the sample number at which the maintenance should be performed.
	TIP: A maintenance can also be dependent upon cycle and sample counter – it must be performed at the event that occurs first.
Reminder:	Off/On; Mode that specifies whether a scheduled maintenance is displayed on the Ready screen.
Archive:	Off/On; Mode that specifies whether a conducted maintenance is entered in the device database.

Timeouts

Use this function to define a timeout for the action that is displayed.

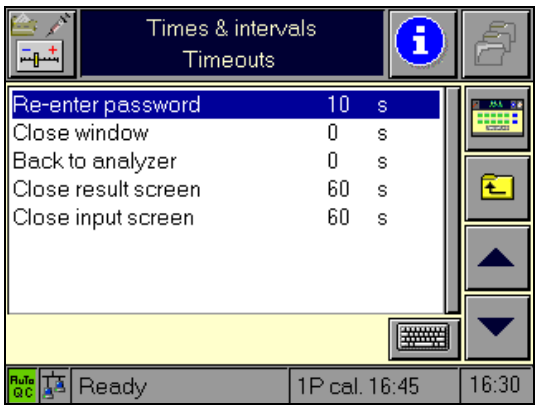


Fig. 56

Activate password:	waiting time before the password entry field in the "analyzer" operating mode's "Ready" screen appears.
Close window:	begins with the opening of the window or the last entry in the window: 10 sec. - infinite.
Back to analyzer:	from the operating modes "Database" and "Setup" back to the "Ready" screen of the "Analyzer" operating mode.
Close result screen:	back to the "Ready" screen of the "Analyzer" operating mode
Close input screen:	starts after completed measurement and final input – back to the "Ready" screen of the "Analyzer" mode.

3.2.3 QC material

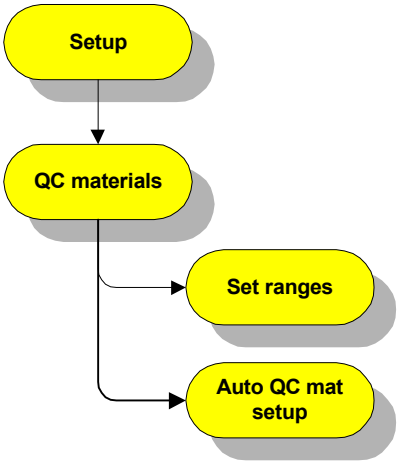


Fig. 57

Set ranges

Use this function to define the QC material (product name, level, lot number, expiration date, and ranges (target values)).

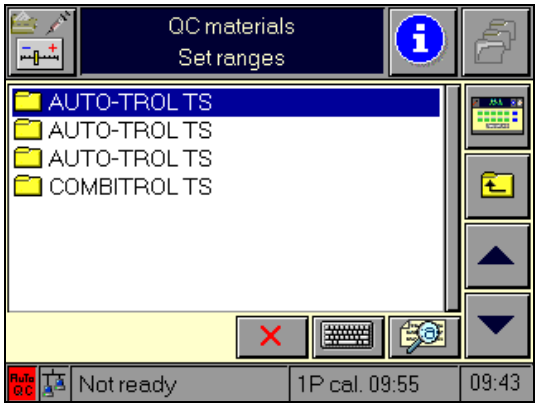


Fig. 58

Please see the Instructions for Use, chapter 5 "**Quality control**" for the procedures of this QC measurement!

AutoQC mat setup

See the Instructions for Use, chapter 5 "**Quality control**"!

3.2.4 Interfaces

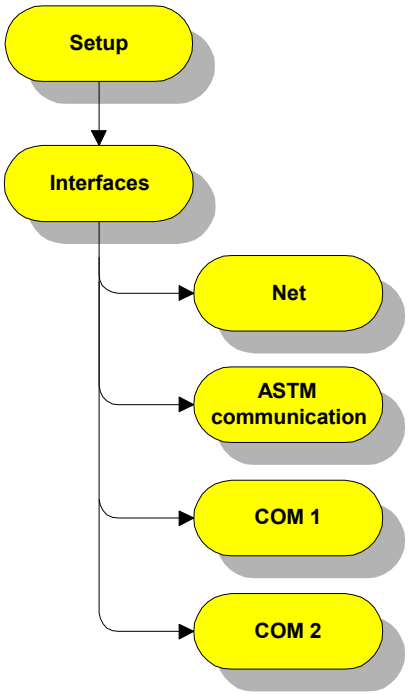


Fig. 59

Network

Use this function to set the instrument-specific network addresses. In addition, you can switch on or off automatic network initialization (performed upon startup of the instrument). If network initialization does not occur upon startup of the instrument, use the button "Initialize" to start this process.

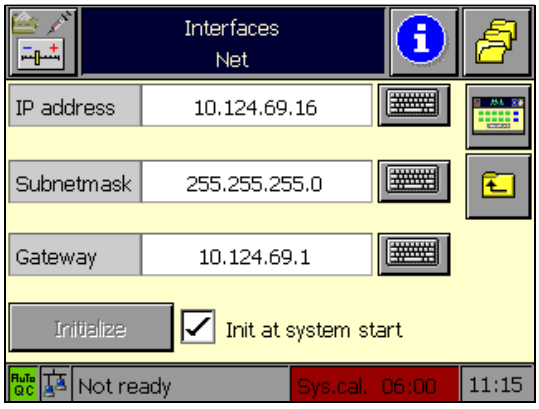
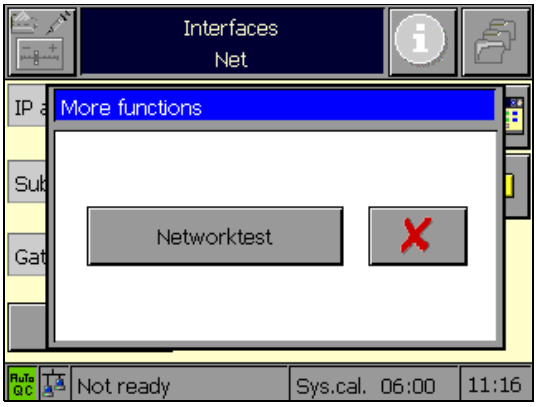


Fig. 60

Networktest

Switch to the following view by pressing the button:



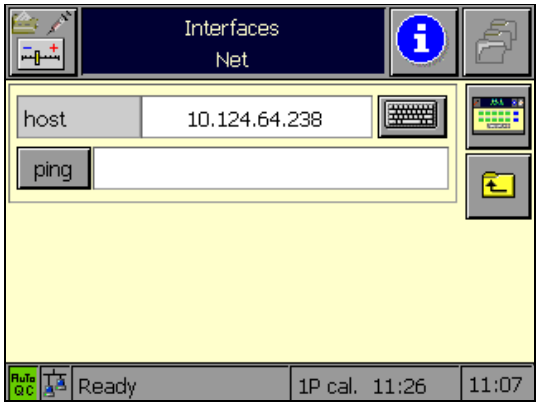


Fig. 61

Use this function to perform a networktest.

Press the "ping" button to check the network interfaces – this requests an echo reply from other instruments.

ASTM communication

This function is used to transfer data from measurements, quality controls, calibrations and maintenance either in serial form or via network.

Using the enter the IP address of the host system and the port address stated by the manufacturer of the host software. With this, you specify where the data are to be sent.

TIP: *If ASTM is assigned via COM 2 interface, then host address and host port can not be entered.*

If the "activated" check box is marked, the data transfer for measurements and quality controls is activated.

If the "Additional data/DC" check box is marked, the data transfer for calibrations and maintenance is activated.

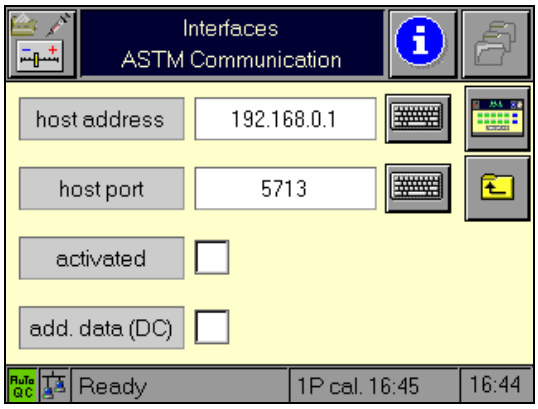


Fig. 62

TIP: *If DataCarePOC (DC) is linked via this interface, the control box* "additional data/DC" *should be activated.*

COM 1

This interface can be assigned to a ticket printer or a host FMT.

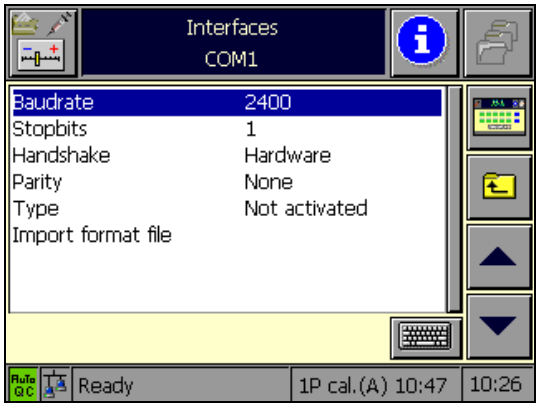


Fig. 63

Use the button to perform the following entries:

Baud rate

Enter the transfer rate

Options: 1200, 2400, 4800, 9600

Stop bits:

The stop bit follows the actual "character bits" in a serial data transfer. It refers to the completeness of the character transfer.

Options: 1, 2

Handshake

Select the desired function for the data transfer.

Options: Xon/Xoff, Hardware, None

Parity

This function ensures that no data is lost during the data transfer or arrives in a defective state.

Options: None, Even, Odd

Type

Select the desired use of the interface.

Options:	Not activated, Ticket printer, Host FMT
Not activated:	The interface is deactivated.
Ticket printer:	The interface is assigned to a ticket printer. The form layout can be created under Windows using a tool specifically supplied by Roche.
Host FMT:	Use this function to issue freely defined reports via serial interface. For more detailed information contact a Roche Diagnostics representative.

Use the button to start the "Import format file" function.

COM 2

ASTM can be assigned to this interface in a serial way. Use this function to transfer data from measurements, quality controls, calibrations and maintenance (see also the section "Interfaces > ASTM communication" on page 3-42).

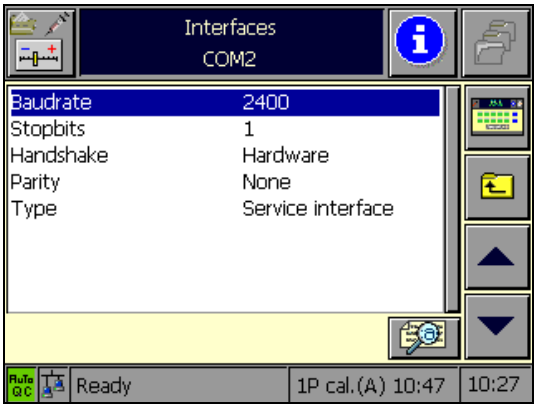


Fig. 64

Use the button to perform the following entries:

Baud rate:	Enter the transfer rate Options: 1200, 2400, 4800, 9600
Stop bits:	The stop bit follows the actual "character bits" in a serial data transfer. It refers to the completeness of the character transfer. Options: 1, 2
Handshake:	Select the desired function for the data transfer. Options: Xon/Xoff, Hardware, None
Parity:	This function ensures that no data is lost during the data transfer or arrives in a defective state. Options: None, Even, Odd
Type:	Service interface, ASTM

TIP: ***In general, the service interface is always deactivated. If this is not the case, it must be deactivated by customer service in the password-protected service area.***

3.2.5 Displays & reports

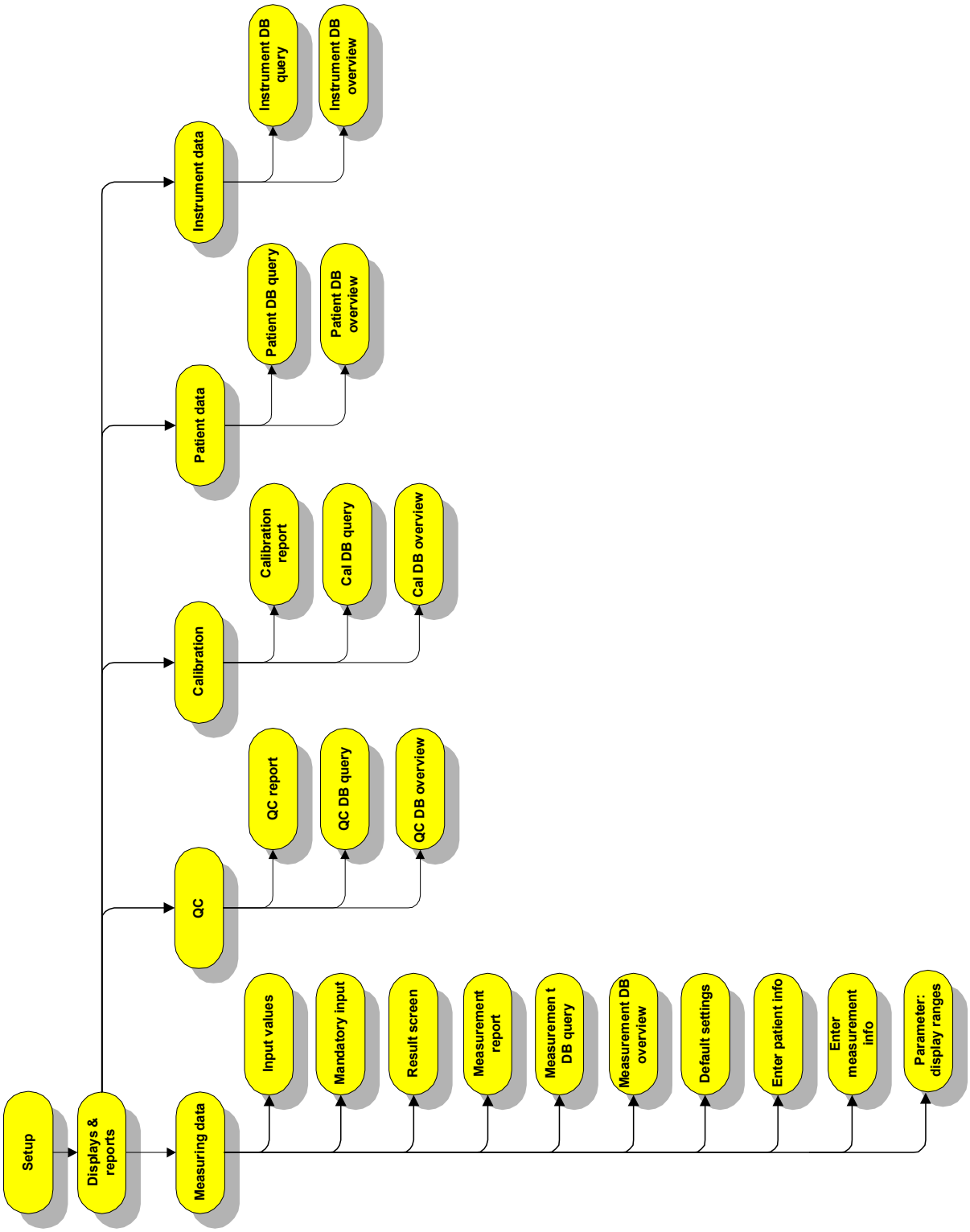


Fig. 65

Measuring data

Input values

Use this function to define the input values that are displayed in the results display.

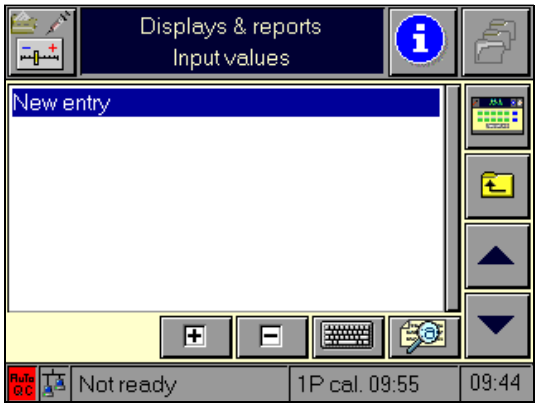


Fig. 66

Use the "+" button to insert a new form ("No name").

Use to enter a new name.

By pressing the button you switch to the following view:

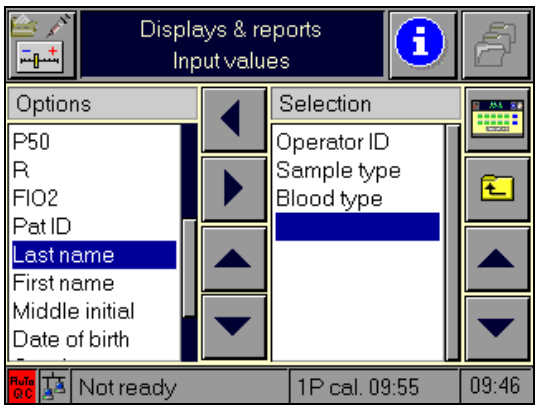


Fig. 67

Press "line up/down" and select a parameter from the left list ("Options").

This list can be expanded with patient data and parameter inputs (see sections "Enter patient info" and "Parameter entry").

Press / to add the selected entry to / remove the selected entry from the selection list.

During a measurement and as soon as the input screen appears, press and select one of the defined forms.

This form remains the standard until a new form is selected.

Mandatory input

In the setup of the input parameters, any of the input parameters can be selected to require a mandatory input by the operator.

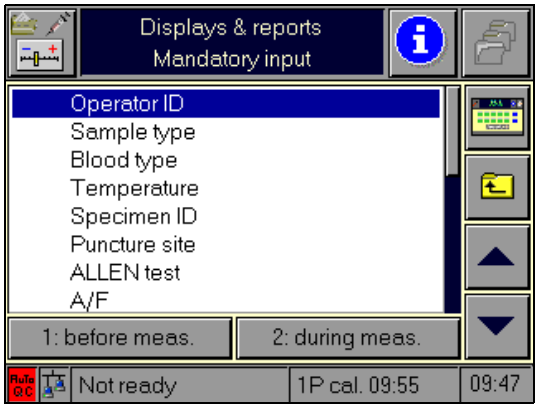


Fig. 68

Select an input parameter and press:

"1:before measurement": you can assign only one input parameter and you must enter it before the measurement

"2:during measurement": it is possible to assign this mandatory input to as many input parameters as desired, but they must be entered during (or after) the measurement.

Result screen

Use this function to define the measurement and calculation values as well as additional information that are shown in the results display.

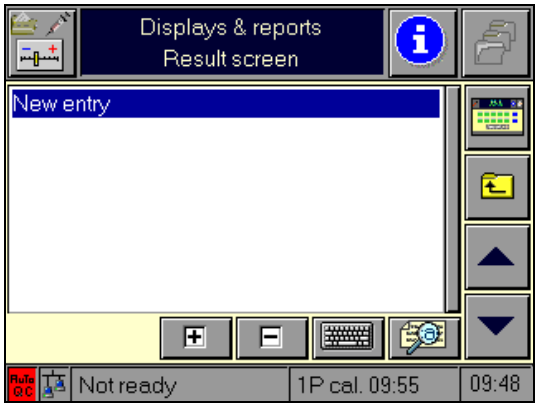


Fig. 69

Use the "+" button to insert a new form ("No name").

Use to enter a new name.

By pressing the button you switch to the following view:

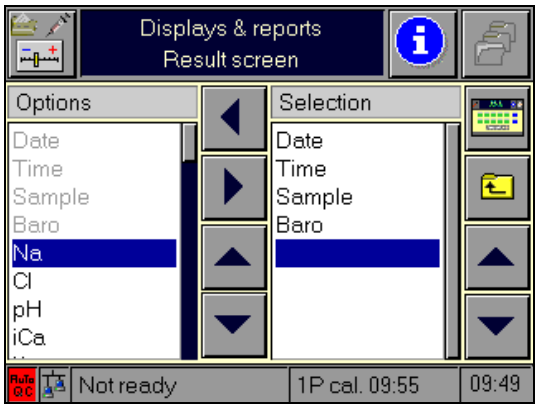


Fig. 70

Press "line up/down" and select a parameter from the left list ("Options").
Press / to add the selected entry to / remove the selected entry from the selection list.
During a measurement and as soon as the results screen appears, press twice.
This form remains the standard until a new form is selected.

Measurement report

Use this function to define the input, default, measurement and calculation values as well as additional information that are printed in the measurement report.

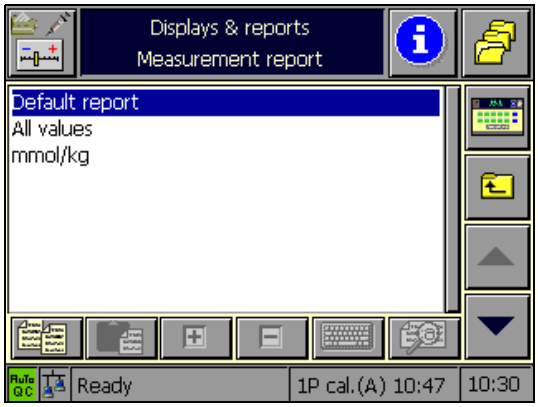


Fig. 71

Use the "+" button to insert a new form ("No name").
Use to enter a new name.

By pressing the button you switch to the following view:

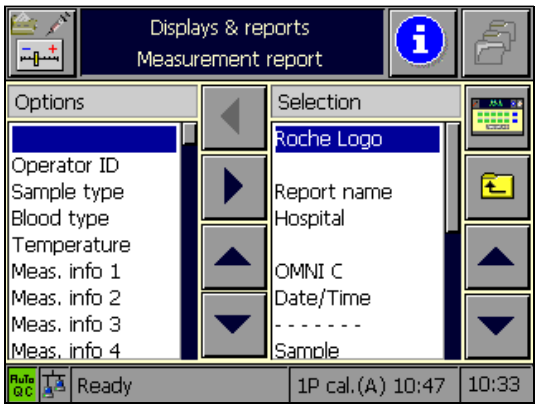


Fig. 72

Press "line up/down" and select a parameter from the left list ("Options").

Press / to add the selected entry to / remove the selected entry from the selection list.

During a measurement and as soon as the input screen appears, press and and select one of the defined reports.

This form remains the standard until a new form is selected.

Number of reports

Switch to the following view by pressing the button:

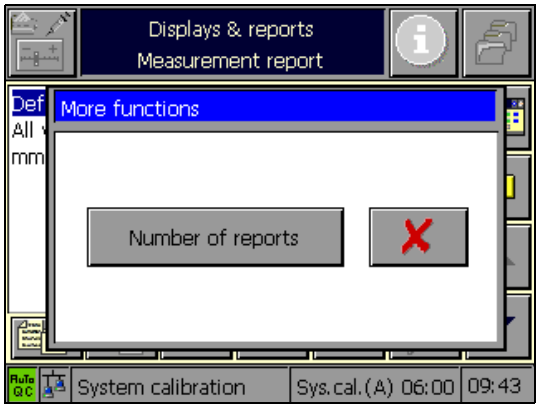


Fig. 73

Use this function to specify how many reports are printed following the measurement.

Press

and select the number of reports.

Measurement DB query

Use this function to set the request criteria for the measurement database in order to limit the results to a reasonable number.

Example: A query that provides all of the measurements of the last month. The last name and first name are to be selected directly during the query.

Use the "+" button to insert a new form ("No name").

Use to enter a name (e.g. "Measurements last month").

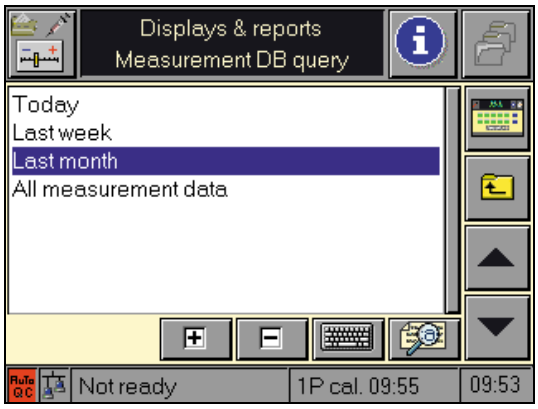


Fig. 74

Press the button twice.

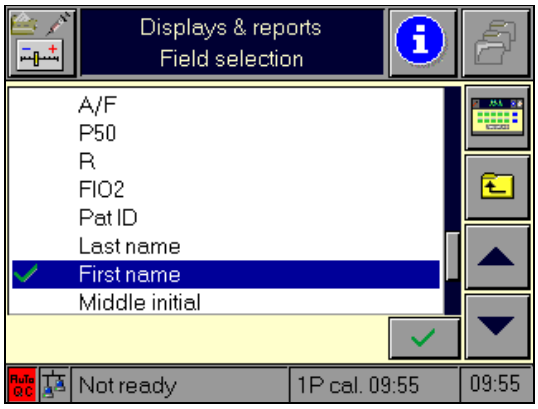


Fig. 75

"Field selection": select "First name" from the list and confirm your selection with .

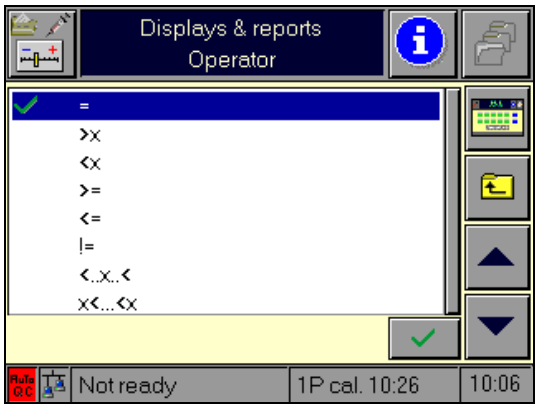


Fig. 76

"Operator": select "=" and confirm your selection with .

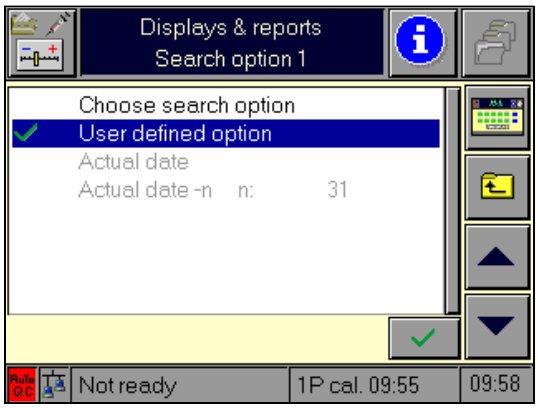


Fig. 77

"Search option 1": select "User defined option" and confirm your selection with . You will then be able to select the first name that you would like to find in the database.

Press twice.

Use the "+" button to insert a new criterion ("last name").

Press the button.

"Field selection": select "Last name" from the list and confirm your selection with .

"Operator": select "=" and confirm your selection with .

"Search option 1": select "User-defined option" and confirm your selection with . You will then be able to select the last name that you would like to find in the database.

Press twice.

Use the "+" button to insert a new criterion ("date").

Press the key.

"Field selection": select "Date" from the list and confirm your selection with .

"Operator": select "<x<" and confirm your selection with .

"Search option 1": select "Actual date". An input field will appear.

Enter "31" days for the last month and confirm your selection with .

"Search option 2": select "Actual date".

TIP: ***Search option 2 is only used with the operators "<x<" and "x<...<x" which require the entry of a value range.***

Press three times.

You can now query the measuring data with the aid of the "Measurements last month" filter in database mode. Enter the first and last name and the date and you will receive the desired measuring data.

Measurement DB overview

Use this function to set the screen display of the measurement database overview.
Use the "+" key to add a new form ("No name"). You can remove it again with "-".

Use to enter a new name.

Press the button.

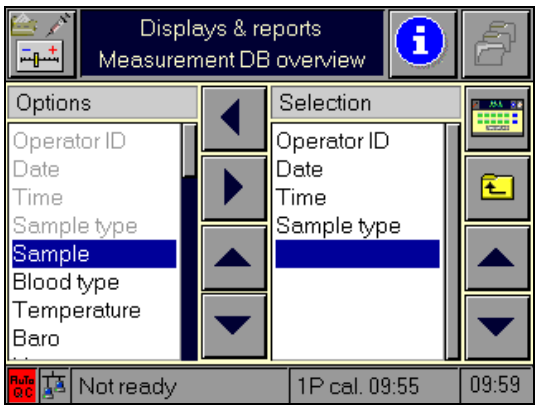


Fig. 78

Press "line up/down" and select a parameter from the left list ("Options").

Press / to add the selected entry to / remove the selected entry from the selection list.

You can assign a view to the listed queries in the "Database – Measuring data" operating mode. Select "All measurement data", for example.

Press the button and and select one of the listed views.

Selection: standard (default view), all, user-defined views.

This view will remain the standard until the selection of a new view.

Default settings

By pressing the "Data entry" button you can define the standard settings for the selected parameter.

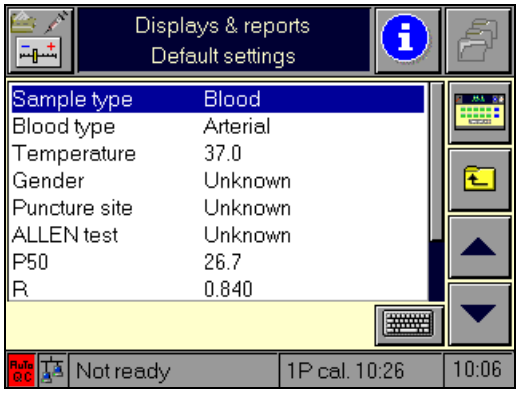


Fig. 79

Enter patient info

Use this function to expand the list of possible input values.

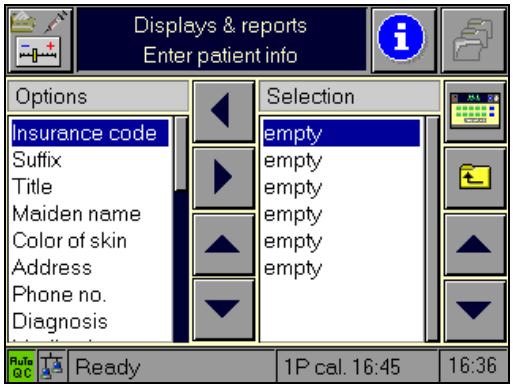


Fig. 80

Enter measurement info

Use this function to expand the list of possible input values.

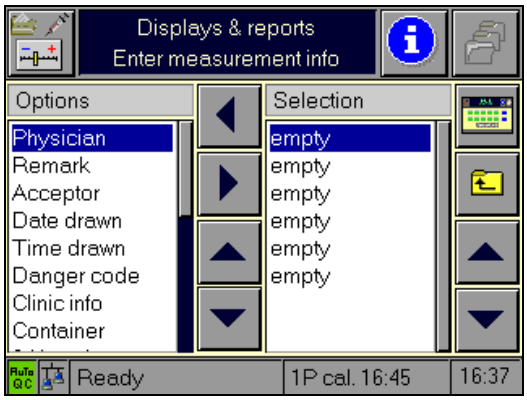


Fig. 81

Parameter: display ranges

Use this function to specify whether normal, critical or no areas are printed on the measurement report and displayed on the result screen.

See also the section "Parameter – Reference/critical ranges" on page 3-31!

QC

QC report

Use this function to activate / deactivate the QC report!

QC DB query

Use this function to establish the request criteria for the QC database.

See "Measurement DB query", page 3-50!

QC DB overview

Use this function to set the screen display of the QC database overview.

See "Measurement DB overview", page 3-52!

Calibration

Calibration report

Use this function to activate / deactivate the calibration report!

Calibration DB query

Use this function to establish the request criteria for the calibration database.

See "Measurement DB query", page 3-50!

Calibration DB overview

Use this function to set the screen display of the calibration database overview.

See "Measurement DB overview", page 3-52!

Patient database

Patient DB query

Use this function to establish the request criteria for the patient database.

See "Measurement DB query", page 3-50!

Patient DB overview

Use this function to set the screen display of the patient database overview.
See "Measurement DB overview", page 3-52!

Instrument data

Event report

Use this function to activate / deactivate the event report.

Instrument DB query

Use this function to establish the request criteria for the instrument database.
See "Measurement DB query", page 3-50!

Instrument DB overview

Use this function to set the screen display of the instrument database overview.
See "Measurement DB overview", page 3-52!

3.2.6 Instrument

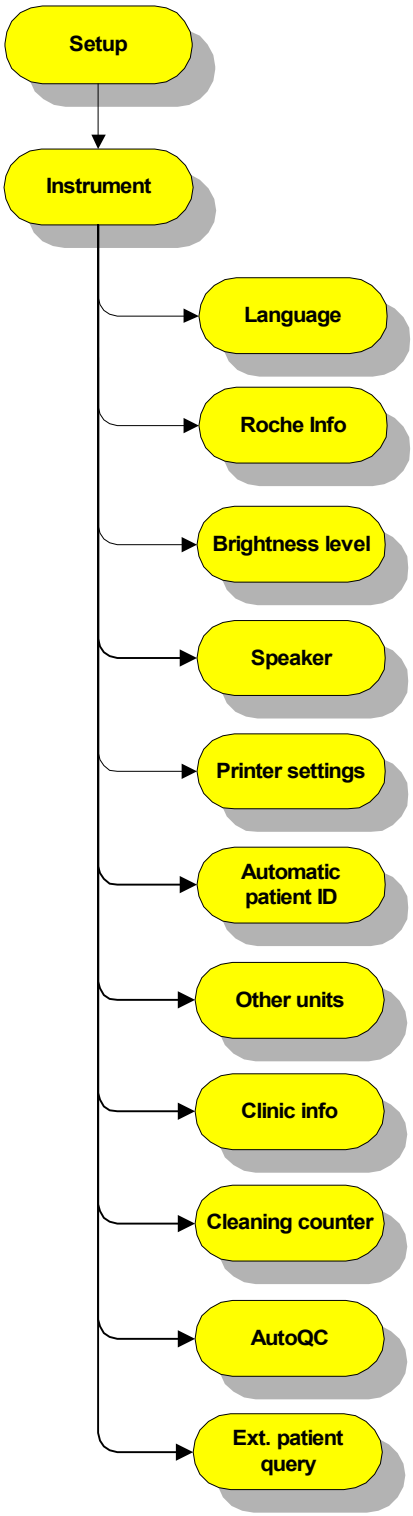


Fig. 82

Language

Use this function to select or load the language that will be used for operation of the Roche OMNI C.

Select the language

Default: English and German

TIP: These languages can not be deleted.

Use the "line up/down" buttons to select your language. Pressing the button activates the language that will be used for operation of the Roche OMNI C.

Fig. 83

Load language

Use the "+" key to add a new language. You can remove it again with "-".

The following screen appears:

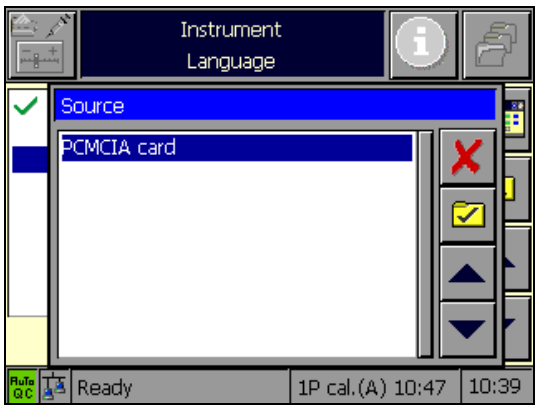


Fig. 84

Select the source for the language to be loaded (e. g. PCMCIA card).

TIP: The PCMCIA card has to contain directory „lng“.

When the source has been selected the following screen appears:

Abb. 85

Select the language and press - the language is loaded and displayed.

Abb. 86

TIP: In addition to the language, the version number of the language file is displayed.

Roche info

Use this function to enter the telephone number, e-mail address, name and postal address of your Roche customer service representative. The input is limited to 28 characters.

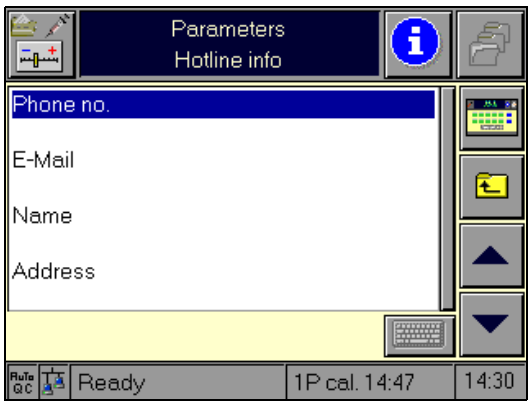


Fig. 87

Press:

"Roche info"

The entered data will be displayed.

Brightness level

Use this function to adjust the brightness of the screen.

Speaker

Use this function to select a melody and to set the volume.

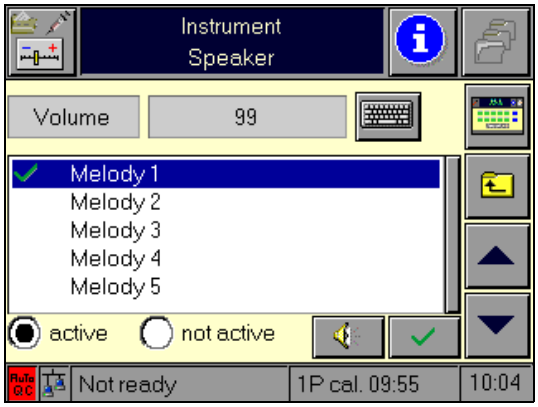


Fig. 88

Printer settings

With this function, you can enter the desired number of empty lines between the printouts as well as activate / deactivate the printer or the cutter.

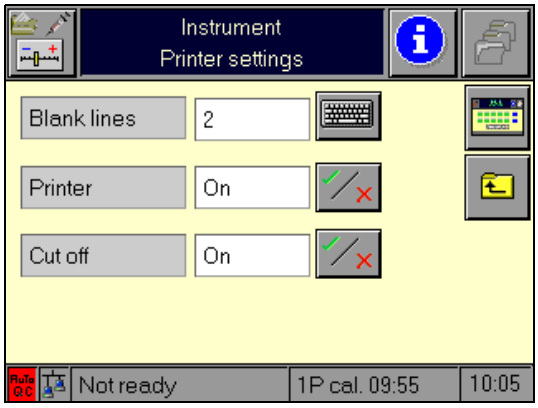


Fig. 89

Automatic patient ID

When this function is activated, the patient ID is assigned automatically by the instrument.

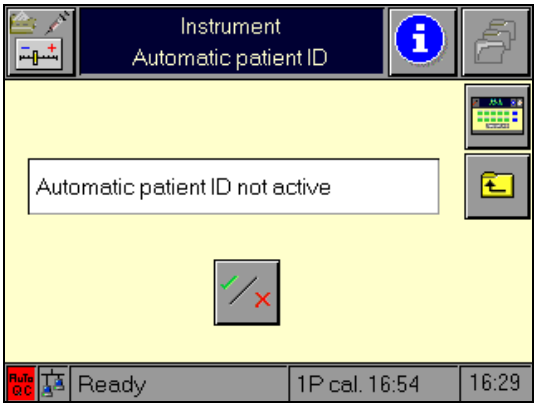


Fig. 90

Other units

Use this function to define SI, standard or other units for the listed parameters.

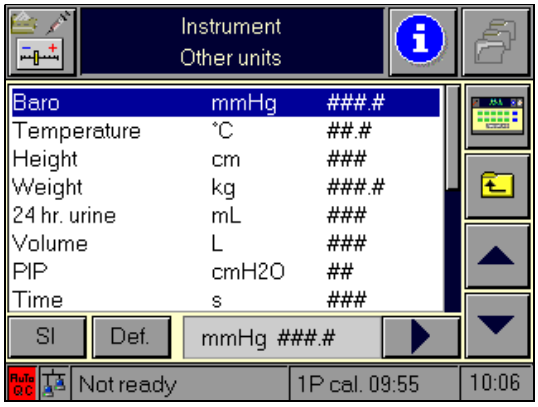


Fig. 91

Designation	Format & unit 1 [Def.]	Format & unit 2	Format & unit 3
Air pressure	xxx.x mmHg	xx.xx kPa	xxx.x mBar
Temperature	xx.x °C	xx.x °F	
Sizes	xxx cm	xxx.x inch	
Weight	xxx.x kg	xxx.x lbs	
24h urine	xxx mL		
Volume	xxx liter		
PIP	xx cmH_2O	xx.xx kPa	
Time	xxx s		
Rate	xxx.x br/min		
Flow rate	xx.xx L/min		

ctO_2	xx.x Vol%	xx.x mL/dL	xx.x mmoL/L
$ctCO_2(B)$	xxx.x mmoL/L	xxx.x mL/dL	xxx.x Vol%
a/AO_2	xx.x %	xx.x	
RI	xx %	x.xx	
MCHC	xx.x g/dL	xx.xx mmol/L	
mV	xxxx.xx mV		
Osm	xxx.x mOsm/kg	xxx.x mmol/kg	
H^+	xxx.x nmol/L		
P/F	xxx.x mmHg		

Clinic info

Use this function to enter information related to your hospital such as its name. The input is limited to 40 characters.

It will then be displayed onscreen and on reports.

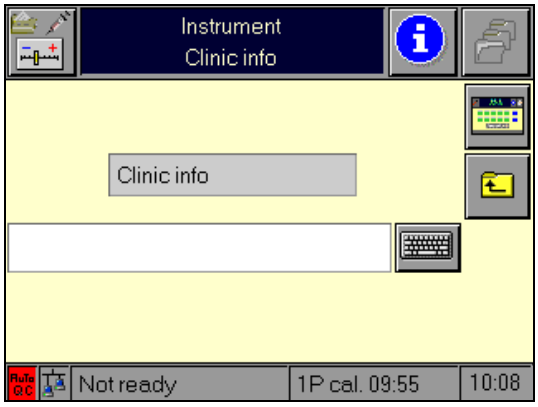


Fig. 92

Cleaning counter

Use this function to set the number of measurements to be performed after which an automatic cleaning will be performed during a system calibration.

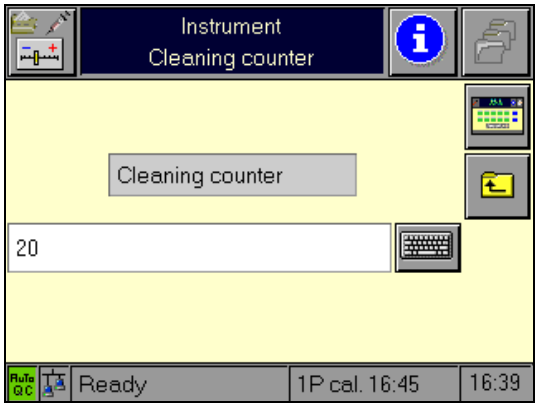


Fig. 93

AutoQC

Use this function to activate/deactivate the AutoQC module if your Roche OMNI C is equipped with one.

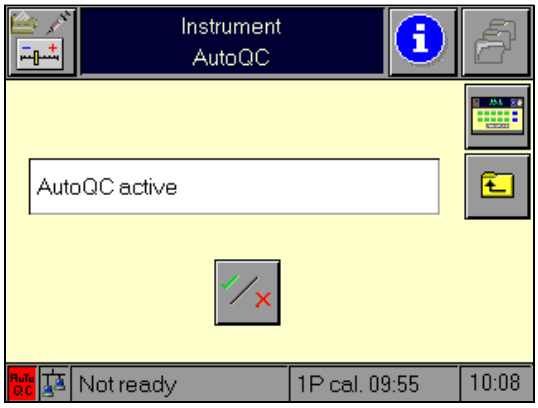


Fig. 94

The AutoQC module is activated during installation of instruments of units already prepared at the factory for use with an AutoQC module (see Instructions for Use, chapter 1 "**Introduction**", section "**Installation**").

Ext. patient query

Use this function to search for patient data stored on a host computer. The search criterion is the patient ID.

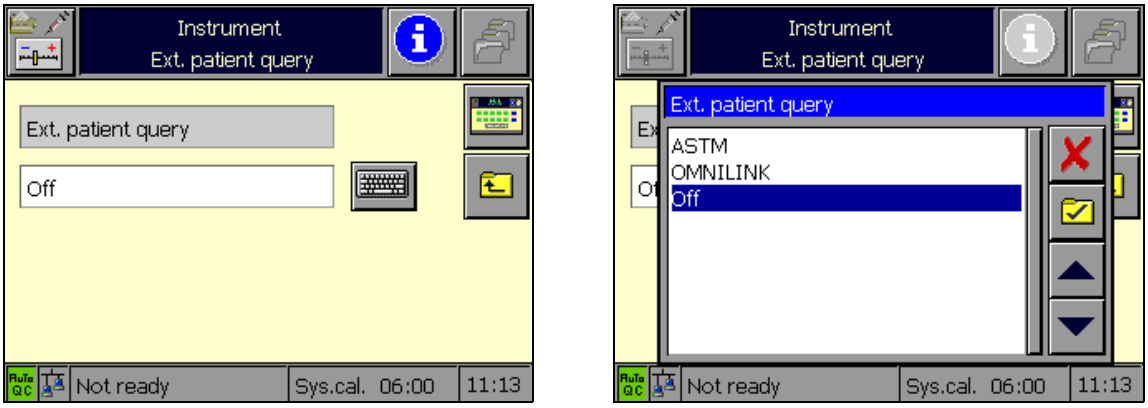


Abb. 95

Use to select the required transfer type.

Options: ASTM, OMNILINK, Off

ASTM: The patient data is searched for using the set ASTM connection (see also Section "Interfaces > ASTM transfer", page 3-42).

OMNILINK: The patient data is searched for using the OMNILINK connection.

Off: The external patient search is deactivated.

3.2.7 Password

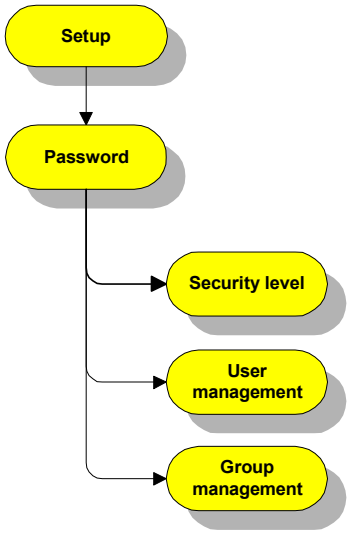


Fig. 96

Security level

Use this function to activate / deactivate the password protection!

User management

Use this function to establish a list of users. The input is limited to 200 users.

Fig. 97

Additional information about the marked entry or about entering passwords, names and user groups

Adding new users to list / removing users from list

Search for users

Sort the user list

Group administration

Fig. 98

Use this function to establish a list that defines all user groups who are permitted to use the instrument. The input is limited to 10 user groups.

It is not possible to delete or alter the group "Administrator."

By pressing the button you switch to the following view:

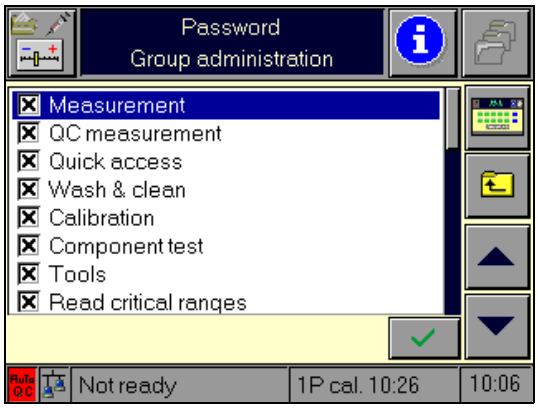


Fig. 99

In this view you see a listing of all accessible features of the instrument.

Use the "line up/down" buttons to select the functions that the selected user group may access. Activate them by pressing .

3.2.8 Service area (password protected)

This area is password protected and is accessible only to authorized personnel or customer service representatives!

3.3 Database

Use this function to retrieve the following data:

- Patient data
- Measuring data
- Calibration data
- QC data
- Instrument data

3.3.1 Patient data

The appearance of this view can be defined by the user (see section "Settings – Measurement DB overview", page 3-52).

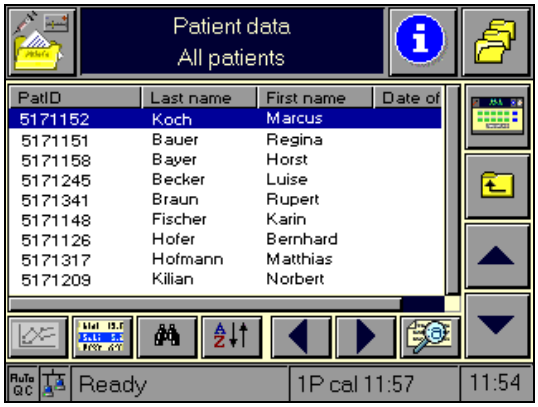


Fig. 100

You can scroll through the view to display all parameters.

Select the marked entry.

The patient data is shown.

The measuring data associated with the selected entry is shown.

See the Instructions for Use, chapter 8 "**Operating modes**", for a more detailed description of the buttons and their features!

3.3.2 Measuring data

The appearance of this view can be defined by the user (see section "Settings – Measurement DB overview",), page 3-52.

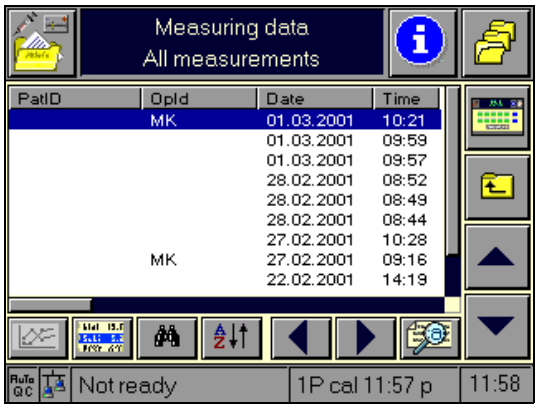


Fig. 101

You can scroll through the view to display all parameters.

Select the marked entry.

The measuring data is shown.

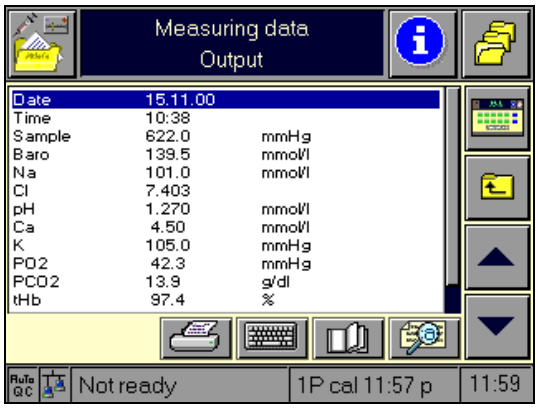


Fig. 102

See the Instructions for Use, chapter 8 "**Operating modes**", for a more detailed description of the buttons and their features!

3.3.3 Calibration data

When you start this function, the overview of the saved calibration data is displayed.

Every line displays a short record of a calibration and contains the date, time, type of calibration, as well as the condition in which the parameters were after the calibration.

You can scroll through the view to display all parameters.

Select the marked entry.

The result screen of the selected calibration data will be displayed.

See the Instructions for Use, chapter 8 "**Operating modes**", for a more detailed description of the buttons and their features!

3.3.4 QC data

When you start this function, the overview of the saved QC data is displayed.

This screen shows all QC materials that were measured up to this point. The data includes level, lot numbers, and the date on which the QC files began.

After you have selected and completed an entry, press the "Zoom" button to receive all available information on the completed QC file.

Every line shows the date, time, operator ID (when available), and the corresponding status of the available parameters.

You can scroll through the view to display all parameters.

Select the marked entry.

The result screen of the selected QC data will be displayed.

See the Instructions for Use, chapter 8 "**Operating modes**", for a more detailed description of the buttons and their features!

3.3.5 Instrument data

The overview of all saved instrument data is displayed when you start this function.

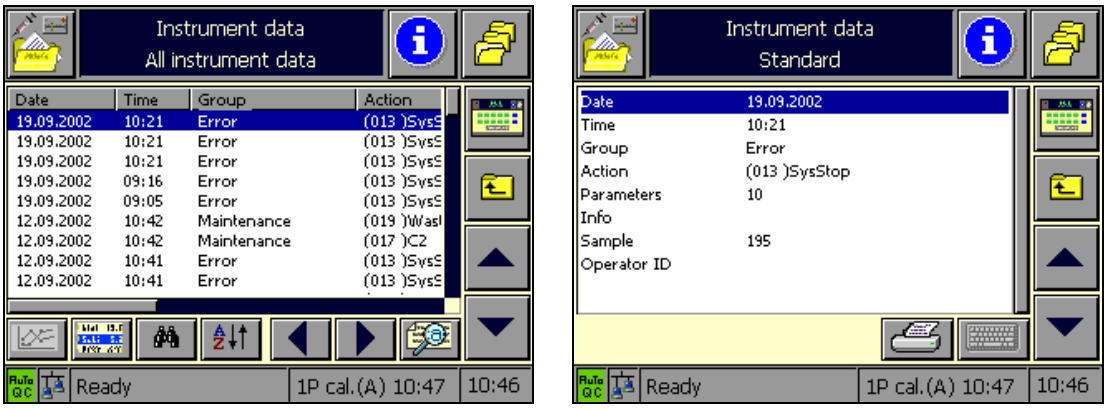


Fig. 103

See the Instructions for Use, chapter 8 "**Operating modes**", for a more detailed description of the buttons and their features!

For further information on the database, please refer to the Instructions for Use, chapter 8 "**Operating modes**"!

3.3.6 Data export

Select with the corresponding database.

Press and then .

The following screen appears:

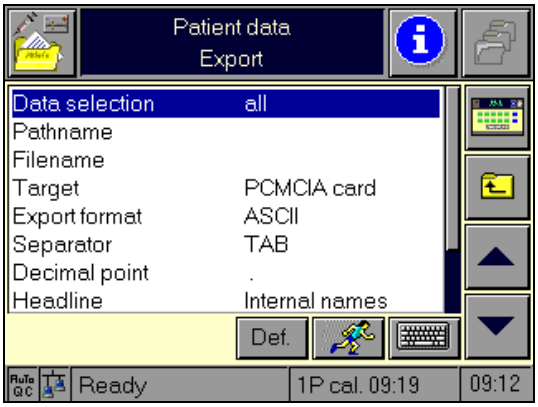


Fig. 104

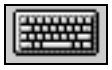
Define the data selection:

selected: if a filter has been applied to the database (all measurements from the prior month, for example); then only this data will be exported (see the Reference manual, chapter **"Operating Modes"**, section "Setup - Displays & reports - Measuring data - Measurement DB query").

marked: all marked data is exported

all: Measurement, patient, calibration, QC, or instrument data is exported

Use to enter file name and path name.

Press  to complete the follwing entries:

- Target (PCMCIA card or net)
- Export format (ASCII or HTML)
- Separator
- Decimal point
- Headline (no display, field name-depending on the country language, internal name-independent of the selected language)
- Unit display (show, don't show)
- Unit conversion (On / Off) - conversion to SI unit or show the set unit.
- Data output (formatted, unformatted)
- After completing all entries, press .
  The data is exported.

TIP: If no entries are necessary press ***to set a standard format.***

3.3.7 Delete data

Select with the corresponding database.

Press and then .

The following screen appears:

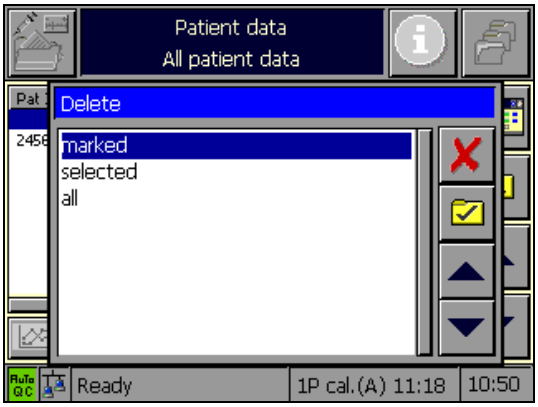


Fig. 105

Use the "Line up/down" buttons to select the function whose data should be deleted:

marked: all marked data is deleted

selected: if a filter has been applied to the database (all measurements from the prior month, for example) only this data will be deleted (see the Reference manual, chapter **"Operating Modes"**, e.g. section "Setup – Displays & reports – Measuring data – Measurement DB query").

all: all data is deleted

TIP: Press ***to delete the selected data.***

4 Performance data

4.1 Specific Performance Characteristics 1-1

4.1.1 Reproducibility 1-1

Material: acetate standard solution (Level 1) 1-1
Material: Acetate standard solution (Level 2) 1-1
Material: Human whole blood 1-1
Material: Human Whole Blood 1-2
Material: Human Plasma 1-2
Material: RNA CVC 123 Level 1 (n = 30) 1-2
Material: RNA CVC 123 Level 2 (n = 30) 1-3
Material: RNA CVC 123 Level 3 (n = 30) 1-3
Material: RNA CVC 123 Level 4 (n = 30) 1-3
Material: RNA CVC 123 Level 5 (n = 30) 1-4
Material: COMBITROL TS Level 1 1-4
Material: COMBITROL TS Level 2 1-4
Material: COMBITROL TS Level 3 1-5

4.2 Linearity, Precision and Recovery 1-6

4.2.1 Whole Blood 1-6

4.2.2 Tonometered whole blood 1-6

4.2.3 Electrolytes in Serum 1-7

4.2.4 Electrolytes in RNA CVC123 1-7

4.2.5 Total Haemoglobin and hematocrit in whole blood 1-8

4.3 Correlation to other Methods 1-9

pH 1-9
PO_2 1-9
PCO_2 1-9
Sodium 1-9
Potassium 1-10
Calcium 1-10
Chloride 1-10
Total haemoglobin 1-10
Hematocrit 1-11
SO_2 1-11

4.4 Interference of tHb/SO_2 1-12

tHb 1-12
SO_2 1-13

4.5 Limitations 1-14

4.5.1 General 1-14

4.5.2 Electrolytes 1-14

4.5.3 Blood Gases 1-14

4.5.4 tHb / SO_2 1-15

4.6 Bibliography 1-16

4 Performance data

4.1 Reproducibility

Typical Within-Run (S_{wr}) and Total (S_T) Precision is determined from 2 runs per day with 2 replicates per run for 20 days on three Roche OMNI C instruments. pH is expressed in pH units, PO_2 and PCO_2 in mmHg, tHb in g/dL, SO_2 and Hct in % and all other values in mmol/L.

Material: acetate standard solution (Level 1)

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
Sodium	138.38	0.3288	0.24	0.7639	0.55
Potassium	2.08	0.0344	1.65	0.0417	2.00
Chloride	114.13	0.2565	0.22	0.8173	0.72
ionised Calcium	1.76	0.0164	0.93	0.0285	1.62

Material: Acetate standard solution (Level 2)

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
Sodium	138.69	0.4352	0.31	0.7694	0.55
Potassium	4.00	0.0178	0.33	0.0230	0.58
Chloride	115.39	0.3772	1.25	0.7492	0.65
ionised Calcium	1.15	0.0144	0.92	0.0156	1.36

Material: Human whole blood

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
pH	7.222	0.0057	0.08	-	-
PCO_2	64.6	0.8547	1.32	1.2495	1.93
PO_2	54.6	0.4426	0.81	1.9952	3.65
Sodium	137.07	0.5762	0.42	-	-
Potassium	3.95	0.0456	1.15	-	-
Chloride	100.74	0.4422	0.44	-	-
ionised Calcium	1.26	0.0127	1.01	-	-
tHb	13.7	0.1663	1.21	-	-
SO_2	78.8	0.3797	0.48	-	-
Hct	42.0	0.8672	2.06	-	-

Material: Human whole blood

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
pH	7.336	0.0044	0.06	-	-
PCO_2	40.2	0.6072	1.51	0.7023	1.75
PO_2	102.8	0.3989	0.39	0.9267	0.90
Sodium	136.23	0.6962	0.51	-	-
Potassium*	4.06	0.0374	0.92	-	-
Chloride	102.26	0.5469	0.53	-	-
ionised Calcium	1.23	0.0118	0.96	-	-
tHb	13.8	0.1802	1.31		-
SO_2	94.9	0.1875	0.20	-	-
Hct	41.3	0.8878	2.15	-	-

**NOTE: Results obtained for Potassium reflects the inconsistent degree of hemolysis, which is characteristic when whole human blood, is tonometered. Refer to performance characteristics of RNA Equil™ to assess the imprecision performance.*

Material: Human plasma

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
pH	7.635	0.0085	0.11	0.0438	0.57
PCO_2	22.2	0.4228	1.90	2.4001	10.81
PO_2	167.9	3.2823	1.95	6.9396	4.13
Sodium	139.83	0.2171	0.16	0.5783	0.41
Potassium	4.08	0.0143	0.35	0.0232	0.57
Chloride	102.37	0.2951	0.29	0.4293	0.42
ionised Calcium	1.06	0.0096	0.91	0.0244	2.30
tHb	-	-	-	-	-
SO_2	-	-	-	-	-
Hct	-	-	-	-	-

Material: RNA CVC 123 level 1 (n = 30)

Parameter	Target	Mean	Recovery	S_{wr}	(CV %)
PCO_2	89.00	89.09	100	0.49	0.55
PO_2	21.00	22.85	109	1.36	5.95
Sodium	87.00	87.45	101	0.22	0.25
Potassium	11.40	11.00	96	0.02	0.18
Chloride	72.00	70.71	98	0.35	0.49
ionised Calcium	2.99	3.30	110	0.02	0.61
Hct	68.00	68.46	101	0.69	1.01

Material: RNA CVC 123 level 2 (n = 30)

Parameter	Target	Mean	Recovery	Swr	(CV%)
pH	7.150	7.164	100	0.002	0.03
PCO_2	73.00	70.02	96	0.39	0.56
PO_2	61.00	56.12	92	3.49	6.22
Sodium	115.00	114.31	99	0.13	0.11
Potassium	2.00	1.99	100	0.01	0.50
Chloride	84.00	80.60	96	0.25	0.31
ionised Calcium	1.40	1.39	99	0.01	0.72
Hct	47.50	47.75	101	0.24	0.50

Material: RNA CVC 123 level 3 (n = 30)

Parameter	Target	Mean	Recovery	Swr	(CV%)
pH	7.410	7.412	100	0.002	0.03
PCO_2	45.00	43.74	97	0.20	0.46
PO_2	101.00	94.03	93	1.35	1.44
Sodium	135.00	134.77	100	0.22	0.16
Potassium	4.40	4.48	102	0.01	0.22
Chloride	101.00	99.81	99	0.16	0.16
ionised Calcium	1.11	1.12	101	0.00	0.00
Hct	42.50	42.45	100	0.16	0.38

Material: RNA CVC 123 level 4 (n = 30)

Parameter	Target	Mean	Recovery	Swr	(CV %)
pH	7.610	7.601	100	0.001	0.01
PCO_2	22.00	21.01	96	0.07	0.33
PO_2	139.00	134.98	97	0.97	0.72
Sodium	163.00	163.32	100	0.13	0.08
Potassium	6.50	6.58	101	0.00	0.00
Chloride	132.00	130.77	99	0.08	0.06
ionised Calcium	0.59	0.59	100	0.00	0.00
Hct	20.50	20.38	99	0.07	0.34

Material: RNA CVC 123 level 5 (n = 30)

Parameter	Target	Mean	Recovery	S_{wr}	(CV %)
pH	7.780	7.784	100	0.003	0.04
PCO_2	13.00	12.26	94	0.12	0.98
PO_2	465.00	459.85	99	3.98	0.87
Sodium	172.00	170.96	99	0.19	0.11
Potassium	1.70	1.81	106	0.02	1.10
Chloride	126.00	127.21	101	0.18	0.14
Ionised Calcium	0.27	0.30	111	0.00	0.00
Hct	23.50	23.15	99	0.17	0.73

Material: COMBITROL TS level 1

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
pH	7.162	0.0036	0.05	0.0074	0.10
PCO_2	67.6	0.5786	0.86	1.2792	1.89
PO_2	53.2	2.0544	3.86	2.7296	5.13
Sodium	119.73	0.3092	0.26	1.3743	1.15
Potassium	2.98	0.0123	0.41	0.0153	0.51
Chloride	85.67	0.3959	0.46	1.7091	1.99
ionised Calcium	1.58	0.0131	0.83	0.0172	1.09
tHb	19.4	0.0453	0.23	0.0635	0.33
SO_2	100	0.000	0.00	0.0000	0.00
Hct	57.1	0.3402	0.60	0.4009	0.70

Material: COMBITROL TS level 2

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
pH	7.398	0.0015	0.02	0.0066	0.09
PCO_2	45.1	0.2514	0.56	0.7574	1.68
PO_2	95.9	1.3162	1.37	2.2630	2.36
Sodium	135.47	0.1555	0.11	0.6942	0.51
Potassium	4.72	0.0064	0.14	0.0158	0.33
Chloride	100.76	0.2128	0.21	0.8923	0.89
ionised Calcium	1.14	0.0063	0.55	0.0139	1.22
tHb	15.2	0.0435	0.29	0.0478	0.31
SO_2	94.3	0.0873	0.09	0.0876	0.09
Hct	42.4	0.2774	0.65	0.3261	0.77

Material: COMBITROL TS level 3

Parameter	Mean	S_{wr}	(CV%)	S_T	(CV %)
pH	7.556	0.0032	0.04	0.0068	0.09
PCO_2	25.1	0.2018	0.80	0.4599	1.83
PO_2	147.0	2.0776	1.41	3.8112	2.59
Sodium	154.41	0.3399	0.22	0.6861	0.44
Potassium	7.02	0.0266	0.38	0.0413	0.59
Chloride	120.61	0.2521	0.21	0.5904	0.49
ionised Calcium	0.61	0.0096	1.57	0.0164	2.69
tHb	8.7	0.0140	0.16	0.0193	0.22
SO_2	85.7	0.0204	0.02	0.0236	0.03
Hct	28.7	0.3613	1.26	0.4492	1.57

4.2 Linearity, precision and recovery

4.2.1 Whole blood

Whole blood was tonometered at 37 °C to various levels of gravimetrically prepared gases with CO_2 and O_2 concentrations certified to ± 0.03% absolute by the manufacturer. Expected and observed values for PCO_2 and PO_2 were corrected to 760 mmHg. Each tonometered level was analysed on two Roche OMNI C Analysers.

PCO_2 (mmHg)

Target	Mean	Swr	Recovery
83.59	82.25	1.11	98
63.22	62.25	1.09	99
20.63	22.33	0.24	108
41.98	42.50	0.77	101

PO_2 (mmHg)

Target	Mean	Swr	Recovery
41.96	41.91	0.17	100
94.40	94.44	0.38	100
145.68	146.84	0.22	101
416.93	419.77	3.36	101

4.2.2 Tonometered whole blood

Runs were made on three Roche OMNI C systems and on one OMNI (bloodgas analyser) after being tonometered to various concentrations of CO_2 and O_2 gas at 37 °C.

				Correlation	
Parameter	**Slope**	**Intercept**	**Coefficient**	**Range [mmol/L]**	**n**
PO_2	1.010	-1.2966	0.9999	40 - 420	40
PCO_2	0.9471	+2.8115	0.9994	20 - 85	40

4.2.3 Electrolytes in serum

Fresh serum samples were collected from healthy volunteers and pooled. The resulting serum was divided into aliquots and either diluted with distilled water, or treated with salts to yield high and low values for sodium, potassium, and chloride and ionised calcium. Each aliquot was verified to have pH within the normal range and was assayed for sodium and potassium using an OMNI. The aliquots were then mixed in varying ratios to provide a linear range of values for each of the analyses, and measured in randomised order on three Roche OMNI C instruments.

				Correlation		
Parameter	**Slope**	**Intercept**	**Coefficient**	**Sy*x**	**Range [mmol/L]**	**n**
Sodium	1.0468	-7.6107	0.9997	0.5164	138 - 202	35
Potassium	0.9345	+0.3278	0.9999	0.3092	3.99 - 17.37	35
Chloride	0.9668	+4.5345	0.9997	0.7758	101 -156	35
ionised Calcium	1.0432	- 0.08899	0.9994	0.0248	2 - 48	35

4.2.4 Electrolytes in RNA CVC123

Aqueous standard solutions from RNA CVC123 measured on each of three Roche OMNI C units.

				Correlation		
Parameter	**Slope**	**Intercept**	**Coefficient**	**Sy*x**	**Range [mmol/L]**	**n**
pH	0.97667	0.17744	0.9998	0.0098	6.88 – 7.78	150
PO_2	0.9972	-4.0635	0.9988	8.0088	21 - 465	150
PCO_2	1.0132	-10.0478	0.9998	4.0406	13 - 89	150
Sodium	0.9922	+0.8107	0.9998	0.60254	87 - 163	150
Potassium	0.9561	+0.2003	0.9995	0.1934	0.2 – 20	150
Chloride	1.0368	-4.9652	0.9988	1.4930	72 - 126	150
ionised Calcium	1.1126	-0.0759	0.9983	0.1246	0.09-4.84	150
Hct	1.0151	-0,57148	0.9998	0.4354	20.5 - 68	150

4.2.5 Total hemoglobin and hematocrit in whole blood

Fresh, whole blood specimens were collected from healthy volunteer donors, centrifuged to concentrate the red cells then, serially diluted with serum to provide a set of linearity standards. Each aliquot was then analysed using an OMNI instruments as reference. The hematocrit value was determined for each of these samples using a microhaematocrit centrifuge.

				Correlation	
Parameter	**Slope**	**Intercept**	**Coefficient**	**Range**	**n**
total Haemoglobin	1.120	-1.164	0.965	6.0-18 [mg/dL]	15
SO_2	1.000	+0.100	0.996	82.5 – 99.6	112
Hematocrit	1.000	-0.600	0.9960	15.8 – 47.6 [%]	112

4.3 Correlation to other methods

During the evaluation comparison studies Roche OMNI C vs. instruments which are already on the market have been performed. In the following table an overview is shown (Y...Roche OMNI C, X...comparison instrument):

pH

Comparison instrument	Slope and intersept	Correlation coefficient	No. of samples
OMNI 9	Y = 0.013 + 1.000 * X	0.992	112
AVL 987	Y = 0.534 + 0.927 * X	0.991	116
Radiometer 700	Y = 0.542 + 0.927 * X	0.993	112
Radiometer 715	Y = 0.415 + 0.945 * X	0.990	62
Bayer Rapidpoint 865	Y = 0.525 + 0.931 * X	0.912	100

PO_2

Comparison instrument	Slope and intersept	Correlation coefficient	No. of samples
OMNI 9	Y = 0.659 + 0.986 * X	0.998	112
Radiometer 625	Y = 3.555 + 0.955 * X	0.984	95
Radiometer 700	Y = 1.445 + 1.005 * X	0.992	112
Bayer Rapidpoint 865	Y = 8.493 + 0.950 * X	0.996	100

PCO_2

Comparison instrument	Slope and intersept	Correlation coefficient	No. of samples
OMNI 9	Y = 0.312 + 1.013 * X	0.996	112
Radiometer 625	Y = -0.291 + 1.022 * X	0.971	97
Radiometer 700	Y = -1.098 + 1.073 * X	0.994	112
Radiometer 715	Y = -0.173 + 1.009 * X	0.981	64
Bayer Rapidpoint 865	Y = 0.375 + 0.971 * X	0.980	100

Sodium

Comparison instrument	Slope and intersept	Correlation coefficient	No. of samples
OMNI 9	Y = -12.588 + 1.085 * X	0.976	112
AVL 987	Y = 17.391 + 0.937 * X	0.937	116
Radiometer 625	Y = -14.700 + 1.100 * X	0.974	93
Radiometer 715	Y = 13.969 + 0.910 * X	0.960	62
Bayer Rapidpoint 865	Y = -11.4 + 1.081 * X	0.955	100

Potassium

Comparison instrument	Slope and intersept	Correlation coefficient	No. of samples
OMNI 9	Y = 0.241 + 0.939 * X	0.983	112
AVL 987	Y = -0.428 + 1.054 * X	0.983	116
Radiometer 625	Y = -0.230 + 1.050 * X	0.994	93
Radiometer 715	Y = -0.173 + 1.062 * X	0.993	64
Bayer Rapidpoint 865	Y = -0.07 + 1.000 * X	0.998	100

Calcium

Comparison instrument	Slope and intersept	Correlation coefficient	No. of samples
OMNI 6	Y = -0.134 + 1.125 * X	0.988	112
AVL 987	Y = -0.106 + 1.131 * X	0.960	116
Radiometer 625	Y = -0.100 + 1.064 * X	0.924	93
Radiometer 715	Y = -0.061 + 1.090 * X	0.994	64
Bayer Rapidpoint 865	Y = -0.025 + 1.050 * X	0.923	100

Chloride

Comparison instrument	Slope and intersept	Correlation coefficient	No. of samples
OMNI 9	Y = 11.854 + 0.898 * X	0.952	112
Radiometer 715	Y = 18.992 + 0.785 * X	0.943	64
Bayer Rapidpoint 865	Y = 8.05 + 0.890 * X	0.961	99

Total hemoglobin

Comparison instrument	Slope and intersept	Correlation coefficient	No. of samples
OMNI 6	Y = -1.164 + 1.120 * X	0.965	91
Radiometer 625	Y = -0.677 + 1.154 * X	0.656	92
Radiometer 700	Y = -0.575 + 1.083 * X	0.993	112
Radiometer 715	Y = -0.161 + 1.083 * X	0.942	64
Bayer Rapidpoint 865	Y = -1.956 + 1.222 * X	0.883	99

Hematocrit

Comparison instrument	Slope and intersept	Correlation coefficient	No. of samples
OMNI 9	Y = -0.600 + 1.000 * X	0.996	112
Radiometer 625 (calculated)	Y = -2.786 + 1.102 * X	0.645	92
Radiometer 715 (calculated)	Y = -3.007 + 1.062 * X	0.742	62
Bayer Rapidpoint 865 (calculated)	Y = -5.15 + 1.200 * X	0.793	100

SO_2:

Comparison instrument	Slope and intersept	Correlation coefficient	No. of samples
OMNI 9	Y = 0.100 + 1.000 * X	0.996	112
Radiometer 625	Y = -78.899 + 1.805 * X	0.821	92
Radiometer 715	Y = -16.276 + 1.161 * X	0.979	64
Bayer Rapidpoint 865	Y = -14.6 + 1.148 * X	0.992	99

4.4 Interference of tHb/SO_2

The tHb/SO_2 module were tested for interference stability in the presence of various chemical substances and pharmaceutical preparations. In accordance with NCCLS recommendations, a certain concentration of interfering substances was added to a control serum for this test, and the serum was then measured again.

tHb

tHb value interference in Roche OMNI C.

Interference substance	Mean value test MVT	Mean value control MVC	N	MVT-MVC
Methylene Blue				
5,0 mg/dL*)	9.2 g/dL %	8.5 g/dL	5	+0.7 g/dL
0,5 mg/dL*)	17.7 g/dL	17.5 g/dL	5	+0.1 g/dL
Indocyanine Green				
0.5 mg/dL	11.4 g/dL %	8.5 g/dL	5	+2.9 g/dL
0.5 mg/dL	22.9 g/dL %	17.7 g/dL	5	+5.2 g/dL
Evan's Blue*)	interference	-	5	n.a.
Hemolysis				
10 %	9.6 g/dL	9.9 g/dL	5	-0.3 g/dL
10 %	17.7 g/dL	18.3g/dL	5	-0.6 g/dL
Ringer-lactate				
50 %	8.4 g/dL	8.2 g/dL	5	+0.2 g/dL
Dextran				
50 %	8.1 g/dL	8.2 g/dL	5	-0.1 g/dL
Beta Carotine				
3 mg/dL	8.5 g/dL	8.3 g/dL		+0.2 g/dL
3 mg/dL	18.0 g/dL	18.0 g/dL		0.0 g/dL

**) For some interferent substances it was not possible to measure the required test range (according NCCLS). In all those cases the Roche OMNI C gives an error message "tHb Interferences".*

SO_2

SO_2 value interference in Roche OMNI C

Interference substance	Mean value test MVT	Mean value control MVC	N	MVT-MVC
Methylene Blue				
5,0 mg/dL*)	52.8 %	99.9 % (at tHb 8,5 g/dL)	5	-47.1
0,5 mg/dL*)	99.9 %	99.9 % g/dL(at tHb 17.5 g/dL)	5	0.0 %
Indocyanine Green				
0.5 mg/dL	99.9%	99.0% g/dL (at tHb 8.5 and 17.7 g/dL)	5	0.0 %
Evan's Blue*)	interference	-	5	n.a.
Hemolysis				
10 %	99.9 %	99.,9 % (at tHb 9.9 and 18.3 g/dL)	5	0.0 %
Ringer-lactate				
50 %	99.9 %	99.9 %	5	0.0 %
Dextran				
50 %	99.9 %	99.9 %	5	0.0 %
Beta Carotine				
3 mg/dL	99.9 %	99.9 %		0.0 %
3 mg/dL	99.7 %	99.7 %		0.0 %

**) For some interferent substances it was not possible to measure the required test range (according NCCLS). In all those cases the Roche OMNI C gives an error message "SO_2 Interferences".*

4.5 Limitations

The performance characteristics are affected by the following sample considerations:

4.5.1 General

A number of substances have been reported to cause physiological changes in blood, serum and plasma analyse concentrations. A comprehensive discussion concerning these and other interfering substances, their blood, serum or plasma concentrations, and their possible physiological involvement is beyond the scope of this method sheet. No significant effect on serum has been demonstrated from bromide, ammonium and iodide.

Unusually high blood lipid content may cause interference in pH measurement, and samples from patients known to have received lipid administration should be labelled so this can be taken into account in the interpretation of results.

As with any clinical reaction, users must be alert to the possible effect on results due to unknown interference from medications or endogenous substances. The laboratory and the physician in light of the total clinical status of the patient must evaluate all patient results.

4.5.2 Electrolytes

Opening and closing the fist with a tourniquet in place results in an increase in potassium levels by as much as 10 to 20%. It is recommended that the blood sample is obtained without a tourniquet, or that the tourniquet be released after the needle has entered the vein and 2 minutes elapsed before the sample is withdrawn.

Because the concentration of potassium inside erythrocytes is much greater than that in the extra cellular fluid, hemolysis should be avoided, and the serum should be separated from the cells as soon as possible after collection.

4.5.3 Blood gases

The preferred test liquid is whole, human blood for all parameters. It is necessary to tonometer blood to obtain values to evaluate accuracy of PO_2 and PCO_2 because patient samples must be considered to be unknown. Tonometry of blood introduces potential errors unrelated to the blood gas system being evaluated, including: accuracy of the gas values used, temperature control and thermostating of the tonometer, humidification of the tonometry gases, duration of tonometry and transfer of the sample from the tonometer to the instrument for analysis.

pH of blood cannot be predicted in tonometry. All tonometered samples analysed in these studies were analysed in duplicate on an AVL 995 to establish correlation. Precision of PO_2 and PCO_2 measurement, as well as pH was evaluated over a 20 day period using two OMNI systems with 2 replicates per run and 2 runs per day using a commercially available solution of reduced bovine haemoglobin which has been demonstrated to be comparable to tonometered whole blood.[1]

1. Mahoney JJ, Wong RJ, Van Kessel AL: Reduced Bovine Hemoglobin Solution Evaluated for Use as a Blood Gas Quality-Control Material. Clin.Chem.39/5, 874-879 (1993).

4.5.4 tHb / SO_2

The Roche OMNI C tHb measurement is sensitive to pathologically rapid sedimentation rates of the erythrocytes, often induced by excessive rate and amounts of rouleaux formation. This is observable as rapid sedimentation and clarification due to erythrocyte aggregates falling to the bottom of the syringe or capillary within minutes of mixing. The Roche Roche OMNI C breaks up most of the rouleaux and other aggregates by rapidly aspirating the whole blood sample with high shear rate, however in rare pathologic cases the rouleaux aggregates persist or reform during the aspiration and can cause a tHb offset.

Please refer to the **Instructions for Use** chapter4, "**Measurement**", section "**Preanalytics**".

4.6 Bibliography

Tietz, Norbert W.,Ed.,Clinical Guide to Laboratory Tests, 2nd Ed., (Philadelphia: W.B. Saunders, Co., 1990).

Burtis C, Ashwood E (Eds.), Tietz Textbook of Clinical Chemistry, 2nd Ed., (Philadelphia: W.B. Saunders, Co., 1994) pp.1354-1360,2180-2206.

Shapiro BA, Peruzzi WT, Kozelowski-Templin R. Clinical Application of Blood Gases, 5th Ed., (Chicago: Mosby, 1994)

Burritt MF, Pierides AM, Offord KP: Comparative studies of total and ionized serum calcium values in normal subjects and in patients with renal disorders. Mayo Clinic Proc. 55:606, 1980.

Kaplan LA, Pesce AJ. Clinical Chemistry: Theory, analysis and correlation, 2nd Ed. (St.Louis: C.V.Mosby Co. 1989) p 590-591.

Mahoney JJ, Wong RJ, Van Kessel AL: Reduced Bovine Hemoglobin Solution Evaluated for Use as a Blood Gas Quality Control Material. Clin.Chem.1991; 39(5): 874-879.

Mahoney JJ, et al. Changes in Oxygen Measurements when Whole Blood is Stored in Iced Plastic or Glass Syringes, Clin.Chem. 1991; 37(7): 1244-1248.

National Committee for Clinical Laboratory Standards. Blood Gas Pre-Analytical Considerations: Specimen Collection, Calibration and Controls; Approved Guideline. NCCLS Document C27-A, (1993).

National Committee for Clinical Laboratory Standards. Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids and Tissue, Second Edition; Tentative Guideline. NCCLS Document M29-T2, (1992).

National Committee for Clinical Laboratory Standards. Percutaneous Collection of Arterial Blood for Laboratory Analysis, Second Edition; Approved Standard. NCCLS Document H11-A, (1992).

National Committee for Clinical Laboratory Standards. Additives for Blood Collection Devices: Heparin; Tentative Standard; NCCLS Document H24-T, (1988).

National Committee for Clinical Laboratory Standards. Evaluation of Precision Performance of Clinical Chemistry Devices, Second Edition; Tentative Guideline. NCCLS Document EP5-T2, (1992).

Snyder John R., Senhauser Donald A, (eds), Administration and Supervision in Laboratory Medicine, 2nd ed, (Philadelphia: J.B.Lippincott Co., 1989).

Meigs JW, Hughes JPW (1952) Acute carbon monoxide poisoning- an analysis of five hundred cases. AMA Arch Ind Hvg 6: 344

Jaffe ER (1981) Methemoglobinemia. J Clin Haematol

Park CM, Nagel RL (1984) Sulfhemoglobinemia. N Engl J Med 310:1579

Zwart A, Buursma A, Oeseburg B, Zijlstra WG (1981) Determination of hemoglobin derivatives with the IL 282 CO-Oximeter as compared with a manual spectrophotometric five-wavelenght method. Clin Chem 27: 1903

Huch R, Huch A, Tuchschmid P, Zijlstra WG, Zwart A (1983) Carboxyhemoglobin concentration in fetal cord blood. Pediatrics 71: 461

Kwant G, Oeseburg B, Zijlstra WG (1989) Reliability of the determination of whole blood oxygen affinity by means of blood gas analyzers and multiwavelength oximeters. Clin Chem 35: 773

Vreman HJ, Ronquillo RB, Ariagno RL, Schwartz HC, Stevenson DK (1988) Interference of fetal hemoglobin with the spectrophotometric measurement of carboxyhemoglobin. Clin Chem 34: 975

Perutz MF (1969) Structure and function of hemoglobin. Harvey Lect. 1967 - 1968, Series 63: 213

Zwaart A, Buursma A, Van Kampen EJ (1984) Multicomponent Analysis of Hemoglobin Derivatives with a Reversed-Optics Spectrophotometer. Clin Chem 30: 373

Zijlstra WG, Buursma A, Meeuwsen- van der Roest WP (1991) Absorption Spectra of human fetal and adult oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and methemoglobin, Clin Chem 37: 1633

J.Toffaletti,Elevations in Blood Lactate, Overview of use in critical care, *Scand J Clin Lab Invest* 1996; 224:
107 – 110

T. Shirey, J. St. Pierre and J. Winkelmann, Cord lactate, pH and blood gases from healthy neonates, *Gynecol Obstet Invest* 1996, 41: 15 –19

J. Toffaletti and D. Hansell, Interpretation of blood lactate measurements in paediatric open-heart surgery and in extracorporeal membrane oxygenation, *Scand J Clin Lab Invest* 1995; 55: 301 – 307

K. Wiener, Whole blood glucose: what are we actually measuring? *Ann Clin Biochem* 1995; 32: 1-8

5 Troubleshooting

5.1 Error messages (sorted by Info No.) 5-1

5 Troubleshooting

5.1 Error messages (sorted by Info No.)

Info No.	Info text	Description	Removal
500	Unsuitable sample type	tHb, SO_2 und Hct can be determined with sample type "blood" only	
501	Reprod. check. pend.	Reproducibility couldn't be checked because of lack of calibration cycles.	• Perform "Calibration for ready“ (see Instructions for Use, chapter 3 "Calibration")
502	Pollution warning	tHb water values warning caused by polluted tHb module, water values are used, but an internal cleaning procedure will be performed during the next system calibration.	• Perform "Internal cleaning of sample path"
1000	Signal noise	The signal noise of an electrode is outside of the specified limits	• Perform "Internal cleaning of sample path" (see chapter 3 "Operating modes", section "Analyzer > System > Wash and Clean") • Perform "Calibration for ready“ (see Instructions for Use, chapter 3 "Calibration") • Check environment conditions (vibrations, electrical fields) • Check electrode for air bubbles in the electrolyte, if necessary change electrode (see Instructions for Use, chapter 6 "Maintenance")
1001	Signal distorted	The sensor signal of an electrode is distorted.	• Perform "Internal cleaning of sample path" (see chapter 3 "Operating modes", section "Analyzer > System > Wash and Clean") • Perform "Calibration for ready“ (see Instructions for Use, chapter 3 "Calibration") • Check environment conditions (vibrations, electrical fields) • Check electrode for air bubbles in the electrolyte, if necessary change electrode (see Instructions for Use, chapter 6 "Maintenance")

Info No.	Info text	Description	Removal
1004	**Out of range**	The calibration result is outside of the specified measuring range.	Check electrode for air bubble in the electrolyte. Change electrode if necessary.
1006	**Out of range**	The measured value is outside of the indicating range	The sample is not suitable for the selected sample type or the measurement result is outside of the specified ranges
1007	**Missing data**	Initial values not o.k.	At least one measured value needed for calculation was not available (e.g. because the respective electrode was deactivated or not calibrated) or was outside of the indicating range
1009	**Baro out of range**	The barometer value is outside of the specified range.	Check the barometric pressure value. Enter barometric pressure value.
1010	**2nd measurement not available**	When calculating a result 2 samples are taken into consideration, but in this case one was missing e.g. calculating the Shunt values.	Perform the missing measurement
1012	**Interferences (2)**	Unsuitable sample, blood sample contains e.g: colouring agents, medicine, infusion or wrong sample type chosen	• Use only specified sample types (human blood and specified QC materials)
1013	**Sensor signal unstable**	The sample was inhomogeneous (contained air, solid particles or had varying density)	• Perform proper preanalytics & sampling.
1022	**Interferences (3)**	The tHb/SO_2 module/algorithm has detected an interference substance,(e.g. COHb ≥ 15%, MetHb ≥ 3%, dye) The SO_2 result was outside of the specified range	• Use only specified samples (human blood)
1023	**Interferences (4)**	The tHb/SO_2 module has detected an interference substance (e.g. COHb ≥ 15%, MetHb ≥ 3% dye). The SO_2 result was outside of the specified range	• Use only specified samples (human blood)
1024	**Out of range (+)**	The tHb result is higher than 25g/dL.	• Use only specified samples (human blood), the measurement result is outside of the specified ranges

Info No.	Info text	Description	Removal
1025	**Out of range (-)**	The tHb result is lower than 3 g/dL.	• Use only specified samples (human blood), the measurement result is outside of the specified ranges
1026	**Out of range (-)**	The SO_2 result is between 0 and 50%	• Use only specified samples (human blood), the measurement result is outside of the specified ranges
1054	**indeterminable**	SO_2 can not be determined because the tHb result is higher than 25 g/dL	• Use only specified samples (human blood), the measurement result is outside of the specified ranges
1055	**indeterminable**	SO_2 can not be determined because the tHb result is lower than 3 g/dL.	• Use only specified samples (human blood), the measurement result is outside of the specified ranges
1070	**Not activated**	Electrode is deactivated for measurement (Electrode status: MS_DUMMY).	• Activate electrode for measurement
1071	**Remote lock**	Electrode is deactivated by remote lockout (OMNILINK) (Electrode status: MS_RMLOCK)	• Remove Remote lockout (OMNILINK)
1072	**Not activated**	Electrode was temporarily deactivated for measurement	• If measurement result is needed, do not temporarily deactivate electrode for measurement.
1073	**Calibration pending**	2 point calibration is missing	Perform "Calibration for ready“ (see Instructions for Use, chapter 3 "Calibration")
1074	**Slope nOK**	2 point calibration failed	• Perform "Calibration for ready“ (see Instructions for Use, chapter 3 "Calibration") • Check electrode, if necessary change electrode (see Instructions for Use, chapter 6 "Maintenance")
1075	**Calibration pending**	1 point calibration is missing	Perform "Calibration for ready“ (see Instructions for Use, chapter 3 "Calibration")
1076	**1P Error**	1 point calibration failed; see calibration report for Error No	Perform "Calibration for ready“ (see Instructions for Use, chapter 3 "Calibration")

Info No.	Info text	Description	Removal
1077	QC lock status	Parameter is locked because a QC measurement failed	*A removal is only allowed if the cause of the lock is known and the error was corrected (e.g. timeout or measurement of wrong ampoule)!* • Automatic correction: proper execution of a QC measurement • Manual correction • Exchange the electrode For details, see Instructions for Use, chapter 5 "Quality control")
1078	Conductivity C2 nOk	Conductivity calibration with solution C2 failed	• Check solution C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C2 docking mechanism • Check sample port and needle (see Instructions for Use, chapter 6 "Maintenance")
1079	Conductivity C1 nOk	Conductivity calibration with solution C1 failed	• Check solution C1 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1 docking mechanism • Check sample port and needle (see Instructions for Use, chapter 6 "Maintenance")
1501	fill FMS	FMS not ready	Switch analyzer off/on
1502	fill FMS	FMS input parameters invalid	Switch analyzer off/on
1503	fill FMS	Wrong valve position(s)	Switch analyzer off/on
1511	fill check	Fill error, measuring chamber left	During measurement: • avoid air bubbles in the sample, • check for sufficient sample volume, • wet sample path (Perform blood measurement) During calibration: • check sample port and needle (see Instructions for Use, chapter 6 "Maintenance")

Info No.	Info text	Description	Removal
1512	fill check	Fill error, measuring chamber right	During measurement: • avoid air bubbles in the sample • check for sufficient sample volume • wet sample path (Perform blood measurement) During calibration: • check sample port and needle (see Instructions for Use, chapter 6 "Maintenance")
1513	fill check	Fill error, location unknown	During measurement: • avoid air bubbles in the sample • check for sufficient sample volume • wet sample path (Perform blood measurement) During calibration: • Check sample port and needle (see Instructions for Use, chapter 6 "Maintenance")
1515	Sample too small	Insufficient sample volume	• Check sample volume according to specifications (see Instructions for Use, chapter 2 "Specifications")
1516	Sample fragmented	The sample contains air bubbles	• Proper sampling (avoid air bubbles in the sample)
1521	fill FMS	FMS not ready	• Switch analyzer off/on
1522	fill FMS	FMS input parameters invalid	• Switch analyzer off/on
1523	fill FMS	Peristaltic pump does not move	• Switch analyzer off/on
1525	fill FMS	Problem with FMS. Improper air / wash packages (timeout=15s exceeded)	• Check pump tube (see Instructions for Use, chapter 6 "Maintenance") • Check FMS volume - call customer service!
1526	fill FMS	Problem with FMS. Missing unfragmented wash package, timeout=10s.	• Check solution C1/C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1/C2 docking mechanisms
1527	fill FMS	Problem with FMS. Missing unfragmented wash package (timeout=15s exceeded)	• Check solution C1/C2 fill level(see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1/C2 docking mechanisms
1541	wash MC	FMS not ready.	• Switch analyzer off/on
1542	wash MC	Wrong valve position(s).	• Switch analyzer off/on

Info No.	Info text	Description	Removal
1545	wash MC	Problem in the washing procedure. SS2 has been empty too early	• Check solution C1/C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1/C2 docking mechanisms
1546	wash MC	Problem in the washing procedure (timeout=10s exceeded)	• Check solution C1/C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1/C2 docking mechanisms
1547	wash MC	Problem in the washing procedure. SS2 has been empty too early	• Check solution C1/C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1/C2 docking mechanisms
1548	wash MC	Problem in the washing procedure (timeout=10s exceeded)	• Perform valve test (see chapter 3, section "Analyzer > System > Test > Valves & Aggregates") • Check FMS tubing, resp. check FMS volume - call customer service!
1554	pos Ref.	No reference contact before reference solution aspiration.	• Check sample port and needle (see Instructions for Use, chapter 6 "Maintenance") • Check measuring chamber for clots (see Instructions for Use, chapter 6 "Maintenance")
1556	pos Ref.	Reference solution aspiration problem	• Check tube and plug of reference electrode (see Instructions for Use, chapter 6 "Maintenance") • Check fill level of reference solution (by auto-preparing) (see chapter 3, section "Analyzer > System > Tools > Auto preparation routines") • Check (and clean) C3 docking mechanism • Check sample port and needle (see Instructions for Use, chapter 6 "Maintenance")
1561	asp. Mix1	FMS not ready.	• Switch analyzer off/on
1562	asp. Mix1	Wrong valve position(s).	• Switch analyzer off/on
1564	check Ref	Proper filling of reference electrode couldn't be checked because of air bubble in the measuring chamber.	• Check sample port and needle (see Instructions for Use, chapter 6 "Maintenance")

Info No.	Info text	Description	Removal
1565	fill Ref	Properly positioning of reference solution not possible, air bubbles in the reference tubing	• Check fill level of reference solution (by auto-preparing), resp. perform “Fill reference electrode” (see chapter 3, section "Analyzer > System > Tools > Auto preparation routines") • Check tube and plug of reference electrode (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C3 docking mechanism • Check sample port and needle (see Instructions for Use, chapter 6 "Maintenance")
1566	Aspirate Mix1	Improper filling of measuring chamber (SS2 is empty too early. Separating air bubble is before MCC-MCO)	• Check solution C1/C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1/C2 docking mechanisms, • Check FMS volume - call customer service!
1567	Aspirate Mix1	Improper filling of measuring chamber (SS2 is empty too early. Separating air bubble is at MCC-MCO).	• Check solution C1/C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1/C2 docking mechanisms, • Check FMS volume - call customer service!
1568	Aspirate Mix1	Improper filling of measuring chamber (SS2 is empty too early. Measuring chamber is filled but air separation bubble before V6).	• Check solution C1/C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1/C2 docking mechanisms, • Check FMS volume - call customer service!
1569	fill MC	Improper filling of measuring chamber (timeout=9s, filling of measuring chamber terminated because of invalid CAL package).	• Check solution C1/C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1/C2 docking mechanisms, • Check FMS volume - call customer service!
1581	Aspirate Mix2	FMS not ready.	• Switch analyzer off/on
1582	Aspirate Mix2	Wrong valve position(s).	• Switch analyzer off/on

Info No.	Info text	Description	Removal
1585	**Aspirate Mix2**	Improper filling of measuring chamber (SS2 is empty too early. Separating air bubble is before MCC-MCO)	• Check solution C1/C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1/C2 docking mechanisms
1586	**Aspirate Mix2**	Improper filling of measuring chamber (SS2 is empty too early. Separating air bubble is at MCC-MCO)	• Check solution C1/C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1/C2 docking mechanisms
1587	**Aspirate Mix2**	Improper filling of measuring chamber (SS2 is empty too early. Measuring chamber is filled but air separation bubble before V6).	• Check solution C1/C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1/C2 docking mechanisms
1588	**fill MC**	Improper filling of measuring chamber (timeout=9s, filling of measuring chamber terminated because of invalid Mix2 package)	• Check solution C1/C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1/C2 docking mechanisms
1601	**Aspirate sample**	Improper filling of measuring chamber (timeout=15s, no sample at SS1)	• Perform proper sample aspiration within 15 seconds • Wet sample path (perform blood measurement)
1602	**Aspirate sample**	Aspiration procedure incorrect. (SS1 sees fluidic residues before measurement has been started)	• Wet sample path (perform blood measurement)
1603	**Aspirate sample**	Aspiration procedure incorrect. (time out=30s, no sample at SS1)	• Perform proper sample aspiration within 30 seconds • Wet sample path (perform blood measurement)
1605	**SS1 inactive**	Sample sensor 1 is not active.	• Check sample sensor calibration - call customer service!
1606	**SS2 inactive**	Sample sensor 2 is not active.	• Check sample sensor calibration - call customer service!
1622	**pos. sample**	Improper filling of tHb/ SO_2 module (timeout=10s, no air separation bubble)	• Perform proper sample aspiration
1623	**pos. sample**	Improper filling of tHb/ SO_2 module (timeout=10s, no sample)	• Perform proper sample aspiration

Info No.	Info text	Description	Removal
1624	pos. sample	Improper filling of tHb/ SO_2 module (timeout=10s, no reproducibility with sample achieved)	• Perform proper sample aspiration (avoid air bubbles in the sample)
1642	pos. sample	Improper filling of measuring chamber (timeout=15s, no air separation bubble) at MCI-MCM)	• Perform proper sample aspiration • Perform "Internal cleaning of sample path“ (see chapter 3, section "Analyzer > System > Wash and clean") • Wet sample path (perform blood measurement)
1643	pos. sample	Improper filling of measuring chamber (timeout=15s, no sample at MCI-MCM)	• Perform proper sample aspiration • Perform "Internal cleaning of sample path“ (see chapter 3, section "Analyzer > System > Wash and clean") • Wet sample path (perform blood measurement)
1644	pos. sample	Improper filling of measuring chamber (timeout=15s, no air separation bubble at MCC-MCO)	• Perform proper sample aspiration • Perform "Internal cleaning of sample path“ (see chapter 3, section "Analyzer > System > Wash and clean") • Wet sample path (perform blood measurement)
1645	pos. sample	Improper filling of measuring chamber (timeout=15s, no sample at MCM-MCO)	• Perform proper sample aspiration • Perform "Internal cleaning of sample path“ (see chapter 3, section "Analyzer > System > Wash and clean") • Wet sample path (Perform blood measurement)
1668	asp. AQC	Improper AutoQC sampling (SS3 detects no sample)	• Perform "Wash AutoQC“ (see chapter 3, section "Analyzer > System > Wash and clean")
1669	asp. AQC	Improper AutoQC sampling (SS3 detects no air).	• Perform "Wash AutoQC“ (see chapter 3, section "Analyzer > System > Wash and clean")
1704	asp. C1	Improper aspiration of calibration solution C1 (time out=30s, no air package at SS2).	• Check tube to air at V2 - call customer service!
1705	asp. C1	Improper aspiration of calibration solution C1 (time out=30s, no calibration solution C1 package at SS2 detected)	• Check solution C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1 docking mechanism • Check sample port and needle (see Instructions for Use, chapter 6 "Maintenance")

Info No.	Info text	Description	Removal
1707	asp. C1	Improper aspiration of calibration solution C1 (time out=30s, no calibration solution C1 package at SS2 detected	• Check solution C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1 docking mechanism • Check sample port and needle (see Instructions for Use, chapter 6 "Maintenance")
1722	C1 pos.	Improper filling of measuring chamber (timeout=10s, no calibration solution C1 at MCI-MCC detected).	• Check solution C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1 docking mechanism • Check sample port and needle (see Instructions for Use, chapter 6 "Maintenance")
1744	asp. C2	Improper aspiration of calibration solution C2 (time out=30s, no air package at SS2 detected).	• Check tube to air at V2 - call customer service!
1745	asp. C2	Improper aspiration of calibration solution C2 (time out=30s, no calibration solution C2 pre-package at SS2 detected)	• Check solution C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1 docking mechanism • Check sample port and needle (see Instructions for Use, chapter 6 "Maintenance")
1747	asp. C2	Improper aspiration of calibration solution C2 (time out=30s, no calibration solution C2 package at SS2 detected).	• Check solution C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1 docking mechanism • Check sample port and needle (see Instructions for Use, chapter 6 "Maintenance")
1762	C2 pos.	Improper filling of measuring chamber (timeout=10s, no calibration solution C2 at MCI-MCC detected).	• Check solution C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1 docking mechanism • Check sample port and needle (see Instructions for Use, chapter 6 "Maintenance")
1782	asp. air	Improper filling of measuring chamber (timeout=15s, measuring chamber is not filled with air)	• Perform V6 test (see chapter 3, section "Analyzer > System > Test > Valves & aggregates • Check tube to air at V9 - call customer service!
1784	asp. air	Timeout=25s, O_2 electrode scan not completed	• Switch analyzer off/on

Info No.	Info text	Description	Removal
1802	pos. Cond.	Improper filling of measuring chamber (air separation bubble has not been detected by MCC-MCO)	• Perform V9 test (see chapter 3, section "Analyzer > System > Test > Valves & aggregates • Check tube to air at V9 - call customer service!
1803	pos. Cond.	Improper filling of measuring chamber (Conditioning solution has not been detected at MCC-MCO)	• Check fill level of conditioning solution (by auto-preparing) (see chapter 3, section "Analyzer > System > Tools > Auto preparation routines") • Check (and clean) C3 docking mechanism
1804	Cond. pos.	Improper filling of measuring chamber (Conditioning solution has not been detected at MCM-MCO)	• Check fill level of conditioning solution (by auto-preparing) (see chapter 3, section "Analyzer > System > Tools > Auto preparation routines") • Check (and clean) C3 docking mechanism
1808	Cond. pos.	End of Mix 1 was not detected at SS1 when refilling	• Wet sample path (Perform blood measurement)
1861	fill FMS	FMS not ready	• Switch analyzer off/on
1862	fill FMS	Wrong valve position(s).	• Switch analyzer off/on
1865	fill Ref	Proper positioning of reference solution not possible, air bubbles in the reference tubing	• Check fill level of Reference solution (by auto-preparing), resp. perform “Fill reference electrode” (see chapter 3, section "Analyzer > System > Tools > Auto preparation routines") • Check tube and plug of Reference electrode (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C3 docking mechanism • Check AutoQC needle - call customer service!
1866	aspirate Mix1	Improper filling of measuring chamber (SS2 is empty too early, air separation bubble before MCC-MCO)	• Check solution C1/C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1/C2 docking mechanisms • Check tubing for leaks (including AutoQC) - customer service! • Check FMS volume - call customer service! (determine FMS volume)

Info No.	Info text	Description	Removal
1867	**aspirate Mix1**	Improper filling of measuring chamber (SS2 is empty too early. Separating air bubble is at MCC-MCO)	• Check solution C1/C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1/C2 docking mechanisms • Check tubing for leaks (including AutoQC) - customer service! • Check FMS volume - call customer service! (determine FMS volume)
1868	**aspirate Mix1**	Improper filling of measuring chamber (SS2 is empty too early. Measuring chamber is filled but air separation bubble before V6)	• Check solution C1/C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1/C2 docking mechanisms • Check tubing for leaks (including AutoQC) - customer service! • Check FMS volume - call customer service! (determine FMS volume)
1869	**aspirate Mix1**	Improper filling of measuring chamber (timeout=9s, filling of measuring chamber terminated because of invalid CAL package)	• Check solution C1/C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1/C2 docking mechanisms • Check tubing for leaks (including AutoQC) - customer service! • Check FMS volume - call customer service! (determine FMS volume)
1900	**asp. O2zero**	Improper aspiration (PO_2 zero-point solution has not been detected at SS1)	• Check fill level of PO_2 zero-point solution (by auto-preparing) (see chapter 3, section "Analyzer > System > Tools > Auto preparation routines") • Check (and clean) C3 docking mechanism, • Check sample port and needle (see Instructions for Use, chapter 6 "Maintenance")
1901	**asp. clean. sol.**	Improper aspiration of cleaning solution (not detected at SS1)	• Check fill level of Cleaning solution (by auto-preparing) (see chapter 3, section "Analyzer > System > Tools > Auto preparation routines") • Check (and clean) C3 docking mechanism • Check sample port and needle (see Instructions for Use, chapter 6 "Maintenance")

Info No.	Info text	Description	Removal
1902	asp. Ref	Improper aspiration of Reference solution (not detected at MCC-MCO)	• Check tube and plug of Reference electrode (see Instructions for Use, chapter 6 "Maintenance") • Check fill level of Reference solution (by auto-preparing) by auto-preparing) (see chapter 3, section "Analyzer > System > Tools > Auto preparation routines") • Check (and clean) C3 docking mechanism
1903	aspirate C1	Improper aspiration of calibration solution C1 (no calibration solution C1 at SS2 detected)	• Check solution C1 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C1 docking mechanism
1904	aspirate C2	Improper aspiration of calibration solution C2 (no calibration solution C2 at SS2 detected)	• Check solution C2 fill level (see Instructions for Use, chapter 6 "Maintenance") • Check (and clean) C2 docking mechanism
1998	Undefined	Undefined error	• call customer service!
2002	FMS out of range	The mixing ratio of the solutions C1 and C2 is outside of the specified range.	• Check solution C1 and C2 fill levels (also for equal levels) (see Instructions for Use, chapter 6 "Maintenance") • Perform valve test (see chapter 3, section "Analyzer > Sytem > Test > Valves & aggregates") • Check FMS tubing - call customer service!
2004	1P Error	2 point calibration failed, because no valid 1 point calibration was available.	• Perform "Calibration for ready“ (see Instructions for Use, chapter 3 "Calibration")
2006	Reproducibility nOK	The standard deviation is outside of the specified range for checking the reproducibility (including tHb)	• Perform "Calibration for ready“ (see Instructions for Use, chapter 3 "Calibration")
2007	Signal noise	A scan criteria for tHb water values was violated	• Perform "Internal cleaning of sample path“ (see chapter 3, section "Analyzer > Sytem > Wash and clean")
2009	Pollution error	tHb water values error caused by polluted tHb module. An internal cleaning procedure will be performed during the next system calibration.	• Perform "Internal cleaning of sample path“ (see chapter 3, section "Analyzer - Sytem > Wash and clean")
2011	Invalid EEPROM data	tHb EEPROM values are incorrect	• Change tHb/SO_2 module - call customer service!

Info No.	Info text	Description	Removal
2012	**Invalid factory cal.**	tHb factory calibration is improperly stored in the EEPROM	• Change tHb/SO_2 module - call customer service!
2014	**Cal. time expired**	Timeout during calibration (failed to start programmed calibration for > 30 min)	• Perform "Calibration for ready“; Do not inhibit programmed calibrations by performing other actions. (see Instructions for Use, chapter 3 "Calibration")
2015	**Ready alarm**	The electrode drift is outside of the specified range	• Perform "Calibration for ready“ (see Instructions for Use, chapter 3 "Calibration")
2016	**conditioning nOK**	Na^+ electrode is in 2 point calibration alarm, because a conditioning is missing	• Check fill level of Conditioning solution (by auto-preparing) (see chapter 3, section "Analyzer > System > Tools > Auto preparation routines") • Perform “Conditioning cycle” (see chapter 3, section "Analyzer > System > Tools") • Check (and clean) C3 docking mechanism,
3001	**Measuring chamber cover open**	• The measuring chamber cover is open • The measuring chamber cover sensor (hall sensor) is defective • The measuring chamber cover cable is defective	• Close measuring chamber cover • Check the measuring chamber cover sensor ("More functions > System > Test > Control sensors > Monitoring sensors") • In case of recurrence, call customer service (check cable, change components if necessary)! ***Consequence actions*** • After opening for longer than 5 seconds: Warm-up • Wash • After changing (an) electrode(s): system calibration

Info No.	Info text	Description	Removal
3002	**Bottle compartment cover open**	• The bottle compartment is open • The bottle compartment cover micro switch is defective	• Close bottle compartment cover • Check to be sure that the bottles are inserted completely • Check the bottle compartment cover micro switch ("More functions > System > Test > Control sensors > Monitoring sensors") • In case of recurrence, call customer service (bottle compartment cover micro switch change if necessary)! ***Consequence actions*** • C1 changed: Prepare solution C1, fill FMS reservoir, conductivity calibration • C2 changed: Prepare solution C2, fill FMS reservoir, conductivity calibration • C3 changed resp. C3 docking mechanism micro switch operated: Prepare C3 solutions • Waste container changed resp. micro switch operated: Waste container fill level measurement
3003	**Flap open**	The flap was opened: - during a measurement - during a calibration - during another system stop - in menu "System" and menu "System" is being closed • The flap detection is defective	• Close flap • Check function of the flap detection board ("More functions functions> System > Test > Control sensors > Monitoring sensors"), change if necessary • In case of recurrence, call customer service! ***Consequence actions*** • Wash
3004	**Analyzer error**	The measurement progress was incorrect	• Press "OK" button • Switch the analyzer off/on • In case of recurrence, call customer service (the electronics is defective, change components if necessary)! ***Consequence actions*** • Wash
3005	**Memory error**	Fundamental software functions can not be performed (memory problems, file system problems), the correct operation of the Roche OMNI C can not be guaranteed	• Press the "Reboot" button • In case of recurrence, call customer service (the electronics is defective, change components if necessary)!

Info No.	Info text	Description	Removal
3006	**Temperature error**	• Measuring chamber (left and right): 37.00 °C ± 0.2 °C • Measuring chamber cover: 37.00 °C ± 0.2 °C • tHb-/SO_2 module: 37.00 °C ± 0.2 °C • A heating device is defective • The measuring chamber cover cable is defective • A temperature sensor is defective	• Reduce / raise the room temperature • In case of recurrence, call customer service!
3009	**Conducitivity cal. error**	The conductivity calibration has failed	• Press the "OK" button (start a system calibration) • In case of recurrence, call customer service! ***Consequence actions*** • System calibration
3010	**AQC cover open**	• The AutoQC cover is open • The AutoQC cover sensor (hnall sensor) is defective	• Close the AutoQC cover • Check the AutoQC cover sensor ("More functions functions > System > Test > Control sensors > Monitoring Sensors"). • In case of recurrence, call customer service (change components if necessary)!
3012	**User system stop**	The automatic fluidic procedure completion of some system stops can be interrupted by a User system stop (by pressing the "Stop" button), e.g. in order to get immediate access to the "More functions" button.	• Press the "OK" button (terminate the User system stop) • In case of recurrence, call customer service! ***Consequence actions*** • Aspirate Mix1
3013	**Fluid pack switch**	• The docking mechanism of Fluid Pack C3 has been opened (micro switch activated) • The Fluid Pack C3 docking mechanism micro switch is defective	• Close docking mechanism Fluid Pack C3 • Check micro switch ("More functions > System > Test > Control sensors > Monitoring sensors"),. • In case of recurrence, call customer service (change if necessary)! ***Consequence actions*** • Auto-preparing of Fluid Pack C3 solutions

Info No.	Info text	Description	Removal
3014	Fill level alarm	• The solutions C1, C2 and/or C3 are empty (below alarm level) or are set to "empty" • The Waste container W is full (above alarm level) • The expiry date of the solutions is exceeded • The on-board lifetime of the solutions is exceeded (C1/C2 = 28 days; C3 = 42 days)	• Change solutions C1, C2 and Pack C3 • Change or empty the Waste container W according to the instructions • In case of recurrence, call customer service! ***Consequence actions*** • C1 changed: prepare solution C1, Fill FMS reservoir, Conductivity calibration • C2 changed: prepare solution C2, Fill FMS reservoir, conductivity calibration • C3 changed resp. C3 docking mechanism micro switch operated: prepare C3 solutions • Waste container changed resp. micro switch operated: Waste container fill level measurement
3015	Waste Container full	Waste container is full	• Change or empty Waste container according to the instructions • Consequence actions • Waste container fill level measurement
3016	Waste Container switch	• The Waste container (W) has been removed • The Waste container micro switch is defective	• Reinsert the Waste container • Check Waste container micro switch ("More functions > System > Test > Control sensors > Monitoring sensors"). • In case of recurrence, call customer service (change if necessary)! ***Consequence actions*** • Waste container fill level measurement
3017	Pump cal. error	• The pump calibration (rotational speed adjustment of the pump) failed	• Check under "More functions > Test > Valves & Aggregates > Peristaltic pump". if values inside the following limits are displayed: Pump volume: 40 - 70µl FMS volume: 920 - 1050µl • If the displayed values are outside of the limits, perform a FMS volume determination and correct the FMS volume value. • In case of recurrence, call customer service! ***Consequence actions*** • Aspirate Mix1 • Conductivity calibration

Info No.	Info text	Description	Removal
3018	**Sample detection failed**	• The sample detection with sample sensors (SS1 and SS2) failed • The sample sensor board is defective	• Press the "OK" button (start a Sample sensor calibration) • In case of recurrence, call customer service! ***Consequence actions*** • Sample sensor calibration • Fill FMS reservoir • Wash
3019	**Out of operation**	The instrument has been taken out of operation	• Perform the installation procedure, see chapter 1 "Introduction", section "Installation".
3020	**Economy mode**	The economy mode has been started manually or automatically	• Manual termination by pressing the "Abort" button • Automatic termination by pre-set stop time
3023	**Waste Container level undefined**	The actually measured waste container fill level differs by more than 4 cm from the calculated/set value	• The waste container fill level must be set roughly (± 4 cm) corresponding to the actual fill level in the waste container • In case of recurrence, call customer service! ***Consequence actions*** • Wash • Waste container fill level measurement
3024	**Flash memory full**	The internal flash memory has less than 8 KB space left for saving additional data	Delete data records (database entries, protocols, log data) in order to free up additional memory (see chapter 8, "Operating modes", section "Database" or Reference Manual, chapter 3, "Operating modes", section "Setup > Displays and reports") ***Important!In order to effectively free up additional memory, the functions "Delete dat" and "Optimize database" have to be activated in this order!***
3025	**PCMCIA memory full**	The PCMCIA card has less than 8 KB space left for saving additional data	Delete data records from the PCMCIA card in order to free up additional memory capacity • insert the card into a PC that has a suitable port, export the data, and then delete the data from the card • reformat the card in the Roche OMNI C (see Reference Manual, chapter 3, "Operating modes", section "System > Test > PC Components > PCMCIA card)

Info No.	Info text	Description	Removal
3026	Data object error	The data access onto objects in the analyzer area failed, the the correct operation of the Roche OMNI C can not be guaranteed	• Press the "Reboot" button • In case of recurrence, call customer service (the electronics is defective, change components if necessary)!
3028	Hardware error	Electronic components do not respond properly	Wait! These errors are automatically self-repaired!
3030	asp. AQC	Initialisation not ok	Switch analyzer off/on
3031	asp. AQC	SS3 calibration not ok	Perform "Wash AutoQC“ (see chapter 3, section "Analyzer > Sytem > Wash and clean")
3032	asp. AQC	The AutoQC needle has not reached the ampoule position.	Perform "AutoQC position test“ (see chapter 3, section "Analyzer > System > Test")
3033	asp. AQC	The AutoQC needle has not reached the start position Z.	Perform "AutoQC position test“ (see chapter 3, section "Analyzer > System > Test")
3034	asp. AQC	The AutoQC needle has not reached the end position Z.	Perform "AutoQC position test“ (see chapter 3, section "Analyzer > System > Test")
3035	wash AQC	The AutoQC needle has not reached the wash position.	Perform "AutoQC position test“ (see chapter 3, section "Analyzer > System > Test")
3036	wash AQC	The AutoQC needle has not reached the ampoule position XY	Perform "AutoQC position test“ (see chapter 3, section "Analyzer > System > Test")
3037	wash AQC	The AutoQC needle has not reached the ampoule position Z (down).	Perform "AutoQC position test“ (see chapter 3, section "Analyzer > System > Test")
3038	wash AQC	The AutoQC needle has not reached the ampoule position Z (up).	Perform "AutoQC position test“ (see chapter 3, section "Analyzer > System > Test")
3039	wash AQC	The AutoQC needle has not reached the ampoule position Z (up)	Perform "AutoQC position test“ (see chapter 3, section "Analyzer > System > Test")
3040	wash AQC	The AutoQC needle has not reached the wash position after back-wash procedure.	Perform "AutoQC position test“ (see chapter 3, section "Analyzer > System > Test")
3051	AQC	AQC timeout (failed to start programmed AQC measurement for > 30 min)	Replace empty AQC mats; Do not inhibit programmed AQC measurements by performing other actions

6 Interfaces

6.1 Pin assignment 6-1

6.1.1 COM 1 and COM 2 6-1

6.1.2 Barcode scanner 6-2

6.1.3 Network 6-2

6.2 Interface description 6-3

6.2.1 COM 1 and COM 2 6-3

6.2.2 Network 6-3

6.2.3 Barcode scanner 6-3

6 Interfaces

The Roche OMNI C is equipped with the following standard interfaces:

- COM 1 ..... RS 232 interface - ticket printer, Host-FMT
- COM 2 ..... RS 232 interface - ASTM
- Barcode scanner ..... PS / 2 DIN 6p female plug
- Network ..... 10 BaseT Ethernet (RJ45)

6.1 Pin assignment

CAUTION: In order to avoid damage to the Roche OMNI C, it is absolutely necessary to compare the pin assignments of the Roche OMNI C with that of the customer's instrument before attaching it to the Roche OMNI C.
Roche Diagnostics assumes no responsibility for damages if this notice is not respected.

6.1.1 COM 1 and COM 2

9 pin SUBMIN D interfaces are available for connection to COM 1 and COM 2.

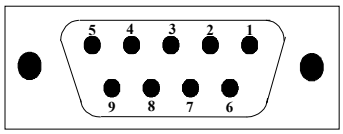


Fig. 1: SUBMIN D interface

Pin 1	DCD	data carrier detected
Pin 2	RxD	receive data
Pin 3	TxD	transmit data
Pin 4	DTR	data terminal ready
Pin 5	GND	signal ground
Pin 6	DSR	data set ready
Pin 7	RTS	request to send
Pin 8	CTS	clear to send
Pin 9	RI	ring indicator

6.1.2 Barcode scanner

A PS/2 DIN 6p plug is available for connection to the barcode scanner.

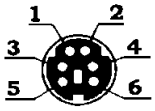


Fig. 2: Interface for the barcode scanner

Pin 1 ..... PC data

Pin 2 ..... NC

Pin 3 ..... GND ..... signal ground

Pin 4 ..... Vcc ..... + 5V power supply

Pin 5 ..... PC CLK ..... clock

Pin 6 ..... NC

6.1.3 Network

Connector standard (also: 10 BaseT), to establish four-wired unshielded twisted pair (UTP) Ethernet connections. RJ-45 is common especially in the USA. In Germany, BNC Cheapernet or AUI cabling are more common.

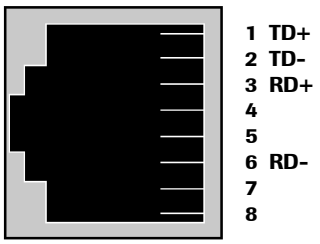


Fig. 3: Network

6.2 Interface description

6.2.1 COM 1 and COM 2

Are accessed through the "Setup" operating mode and are definable RS 232 C interfaces.

Always use a filter adapter when using the serial interfaces.
Please order them from your customer service representative.

COM 1: ticket printer

COM 2: serial interface for general use

6.2.2 Network

10 BASE-T is a sub-category of Ethernet data transfer technology. In its name, 10 stands for 10 Mbps, BASE stands for basis band, and T for twisted pair cable.

10 BASE-T is the most commonly used data transfer technology worldwide.

Please refer to chapter 3 "**Operating modes**", section "**Setup – Interfaces – Network**" for information on setting the instrument-specific network address.

6.2.3 Barcode scanner

The reading unit is preprogrammed for the following code types:

- UPC-E
- EAN-8, EAN 13, EAN 128
- ISBN
- ISSN
- JAN
- Interleave 2 of 5
- Code 11, Code 39, Code 93, Code 32, Code 128
- Codabar
- MSI/Plessey
- BC-412
- China post code

7 Theoretical foundations

7.1 Functionality of the electrodes 7-1

7.1.1 BG electrodes 7-1

PO_2 electrode 7-1
PCO_2 electrode 7-1
pH electrode 7-1
Reference electrode 7-1

7.1.2 ISE electrodes 7-2

Na^+ electrode 7-2
K^+ electrode 7-2
Ca^{2+} electrode 7-2
Cl^- electrode 7-2

7.1.3 tHb / SO_2 module 7-3

7.2 The safety data sheets of the solutions 7-4

7.2.1 C1 Calibration solution 1 7-5

7.2.2 C2 Calibration solution 2 7-8

7.2.3 C3 Fluid Pack 7-11

7.3 Calibration procedure 7-14

7.3.1 BG / ISE calibration 7-14

Reliability of the calibration procedure 7-14

7.3.2 Calibration of the conductivity system as part of the mixing system 7-14

7.3.3 tHb/SO_2 module calibration 7-15

Factory calibration 7-15
1P Calibration 7-15

7.4 Parameters and calculations 7-16

7.4.1 Conversion table for units 7-16

7.4.2 Units of calculated parameters 7-16

7.4.3 Equations 7-17

7 Theoretical foundations

7.1 Functionality of the electrodes

7.1.1 BG electrodes

PO_2 electrode

The PO_2 electrode is a Clark electrode. This means that oxygen diffuses through a membrane to a wire with electrically negative potential within this electrode. This is where oxygen is reduced, by which electrical current is created that is proportional to the oxygen within the sample. It is possible to measure this current.

PCO_2 electrode

The PCO_2 electrode is a Severinghouse model. This means that CO_2 diffuses through a membrane, similar to the oxygen electrode. An electrolyte is located inside the electrode. The diffused CO_2 alters the pH value of this electrolyte. A pH glass electrode measures this pH alteration, which is proportional to the PCO_2 of the sample.

pH electrode

That is a flow-through pH glass electrode that contains a pH-sensitive glass capillary. The housing is filled with buffered electrolyte. Depending on the sample's pH value, electrical potential is generated on the interface between the glass capillary container and the sample. This potential can be measured using a second electrode, the reference electrode (potentiometric measurement).

Reference electrode

All other electrodes provide signals that are based on the contents of the sample to be measured. The reference electrode must always produce the same signal, regardless of the sample's composition. This is achieved by mixing the sample flow with a liquid of a higher KCl concentration (reference solution). The part of the reference solution that is in contact with the sample is renewed after every sample. Inside the electrode is a chloride-sensitive electrode that is in contact with the reference solution flow. Because the concentration of the reference solution does not change, the chloride electrode's signal also does not change. This allows the reference electrode to delivery a signal independent of potential.

7.1.2 ISE electrodes

Na^+ electrode

This electrode is constructed similarly to a pH electrode, but contains a sodium-sensitive glass capillary. Like the pH electrode, it needs a reference electrode in order to operate properly (potentiometric measurement).

K^+ electrode

The active membrane portion of the potassium electrode is localized in the middle of the sample channel and consists of emollient PVC, valinomycin and other additives. The signal emerges when potassium moves from the sample into the boundary layer of the membrane and generates an electrical potential that can be measured.

Ca^{2+} electrode

The calcium electrode is a potentiometric sensor that works much like the potassium sensor. Instead of valinomycin, a synthetically produced neutral carrier is used that enables the transfer of the ionized calcium into the membrane. This electrode detects only the ionized fraction of the calcium, which is available inside the sample.

Cl^- electrode

The chloride electrode works similarly to the potassium electrode and uses a chloride-sensitive ion exchanger instead of valinomycin.

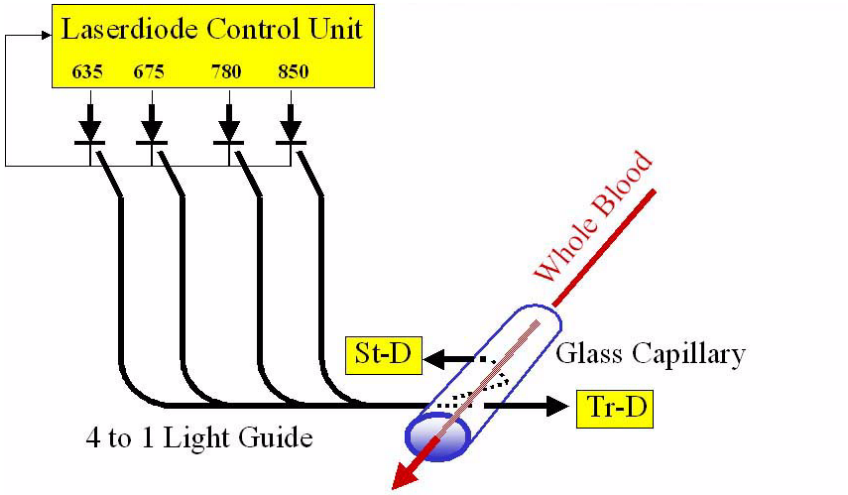
7.1.3 tHb / SO_2 module

The measurement method of this new model is based on the measurement of absorption in whole blood by exploiting the light scatter of the red blood cells.

Laser light sources are used in the module to optically excite a measurement cuvette filled with whole blood. The radiated light is attenuated in whole blood. The amount of attenuation depends on the concentration of the hemoglobin derivatives and their specific absorption.

The blood's specific attenuation is determined for each wavelength from the measurement of scattered light.
To determine the level of absorption, the unattenuated excitement intensity of the light source must also be known; the measurement is performed with a cuvette filled with Mix 1 using the transmission detector.

The wavelength-specific absorption can be calculated from the relation of scattered light intensity (of whole blood) to transmission intensity (of water) by using the calibration function.



St-D = scattered light detector

Tr-D = transmission detector

Fig. 1

7.2 The safety data sheets of the solutions

Use of calibration solutions that were not produced by Roche may lead to an invalidation of the instrument's guarantee.

All reagents are suitable only for diagnostic in-vitro use!

The following solutions are used:

- C1 calibration solution 1
- C2 calibration solution 2
- C3 fluid pack: solution for calibrating the PO_2 zero point
  solution for conditioning the Na^+ electrode
  cleaning solution
  reference solution

7.2.1 C1 Calibration solution 1

Safety Data Sheet

Roche

Date: 20.11.2001 Date of printing: 20.11.2001 Page 1 of 3

1. Name of substance/preparation and company

1.1 Commercial product:	**Calibration Solution C 1 (OMNI C)**
Cat.-No.:	3144046
1.2 Company:	Roche Diagnostics GmbH Sandhoferstr. 116 D-68305 Mannheim Tel. ++49-621-7590 Information obtainable from: ++49-621-759-2763 or ++49-621-759-4848
1.3 In Emergencies:	Central Works Security Roche Diagnostics GmbH ++49-621-759-2211 Centre for Detoxification: Mainz ++49-6131-232466-232467 München ++49-89-19240

2. Composition/Information on constituents

Contains: No hazardous substances in reportable quantities.

Notes: There is at present no information or indication of hazardous property.

3. Hazards identification

Warnings: The usual precautions taken when handling chemicals should be observed.

Notes: Substance slightly hazardous to water and ground water

4. First aid measures

First aid: Eye contact: Flush eyes with water.
Skin contact: Wash off with water.
Ingestion: Seek medical advice.

Instructions for physician: Symptomatic treatment by a physician.

5. Fire-fighting measures

Extinguishing media: No restriction

Thermal decomposition: Dangerous decomposition is not anticipated.

6. Accidental release measures

After spillage: Dilute spilled substance with plenty of water and absorb.

Absorbent material: No restriction.

Damage limitation: Special measures to limit damage are not necessary.

7. Handling and storage

7.1 Handling: Substance or preparation itself does not burn.
No special requirements.

7.2 Storage: Store at room temperature.

Do not store with: No restriction

7-5

Safety Data Sheet

Roche

Date: 20.11.2001 Date of printing: 20.11.2001 Page 2 of 3

Commercial product: **Calibration Solution C 1 (OMNI C)**

8. Exposure controls/personal protection

TLV:	undefined
Respiratory protection:	none
Eye protection:	no
Hand protection:	One-way gloves
Hygiene:	Wash hands before breaks and at the end of the work.

9. Physical and chemical properties

Physical state:	liquid
Miscible with water:	yes
pH:	ca. 9,2
Flash point:	no data available

10. Stability and reactivity

Hazardous Reactions:	None known when used appropriately.
Hazardous decomposition products:	None

11. Toxicological information

LD50 oral	not known
LD50	not known
LD50 skin	not known
LD50 inhal	not known
Toxicologic information:	Intoxication has so far not become known.

12. Ecological information

Hazards:	Substance slightly hazardous to water and ground water

13. Disposal considerations

Waste disposal route:	Used reagent can be disposed off in waste water in accordance with local regulations.
Disposal of emptied packs:	Dispose of empty packs via local recycling or waste disposal routes - if necessary, clean them beforehand.

14. Transport information

RID/ADR:

ICAO/IATA: UN-No.:

IMDG-Code: MFAG:

EMS:

Proper Shipping Name:

Notes: Is not subject to current regulations for transportation of hazardous goods (GGVS/ADR, GGVE/RID, IMDG, IATA/ICAO).

7-6

Safety Data Sheet

Roche

Date: 20.11.2001 Date of printing: 20.11.2001 Page 3 of 3

Commercial product: **Calibration Solution C 1 (OMNI C)**

15. Regulatory

Notes: This product must be not labeled in accordance with EEC directive 67/548 and 88/379.

16. Other information

The information herein is believed to be correct as of the date hereof but is provided without warranty of any kind. The recipient of our product is responsible for ensuring that, where applicable, existing laws and guidelines are observed.
Special permission has been granted in accordance with EU Directive 88/379, Article 9, which permit small packages of up to 125 ml or g containing materials that are harmful to health or irritant to be unlabelled with the hazard identification information given in the safety data sheet.

7-7

7.2.2 C2 Calibration Solution 2

Safety Data Sheet

Roche

Date: 14.03.02 Date of printing 06.08.02 Pag 1 of 3

1. Name of substance/preparation and company

1.1 Commercial product:	**Calibration Solution C2 (OMNI C)**
Cat.-No.:	3144020
1.2 Company:	Roche Diagnostics GmbH Sandhoferstr. 116 D-68305 Mannheim Tel. ++49-621-7590 Information obtainable from: ++49-621-759-2763 or ++49-621-759-4848
1.3 In Emergencies:	Central Works Security Roche Diagnostics GmbH ++49-621-759-2203 Centre for Detoxification: Mainz ++49-6131-232466-232467 München ++49-89-19240

2. Composition/Information on constituents

Contains: No hazardous substances in reportable quantities.

Notes: There is at present no information or indication of hazardous property.

3. Hazards identification

Warnings: The usual precautions taken when handling chemicals should be observed.

Notes: Substance slightly hazardous to water and ground water

4. First aid measures

First aid:	Eye contact: Flush eyes with water. Skin contact: Wash off with water. Ingestion: Seek medical advice.
Instructions for physician:	Symptomatic treatment by a physician.

5. Fire-fighting measures

Extinguishing media:	No restriction
Thermal decomposition:	Dangerous decomposition is not anticipated.

6. Accidental release measures

After spillage:	Dilute spilled substance with plenty of water and absorb.
Absorbent material:	No restriction.
Damage limitation:	Special measures to limit damage are not necessary.

7. Handling and storage

7.1 Handling:	Substance or preparation itself does not burn. No special requirements.
7.2 Storage:	Store at room temperature.
Do not store with:	No restriction

7-8

Safety Data Sheet

Roche

Date: 14.03.02 Date of printing 06.08.02 Pag 2 of 3

Commercial product: **Calibration Solution C2 (OMNI C)**

8. Exposure controls/personal protection

TLV:	undefined
Respiratory protection:	none
Eye protection:	no
Hand protection:	One-way gloves
Hygiene:	Wash hands before breaks and at the end of the work.

9. Physical and chemical properties

Physical state:	liquid
Miscible with water:	yes
pH:	ca. 5,2
Flash point:	no data available

10. Stability and reactivity

Hazardous Reactions:	None known when used appropriately.
Hazardous decomposition products:	None

11. Toxicological information

LD50 oral	not known
LD50	not known
LD50 skin	not known
LD50 inhal	not known
Toxicologic information:	Intoxication has so far not become known.

12. Ecological information

Hazards:	Substance slightly hazardous to water and ground water

13. Disposal considerations

Waste disposal route:	Used reagent can be disposed off in waste water in accordance with local regulations.
Disposal of emptied packs:	Dispose of empty packs via local recycling or waste disposal routes - if necessary, clean them beforehand.

7-9

Safety Data Sheet

Roche

Date: 14.03.02 Date of printing 06.08.02 Pag 3 of 3

Commercial product: **Calibration Solution C2 (OMNI C)**

14. Transport information

RID/ADR:

ICAO/IATA: UN-No.:

IMDG-Code: MFAG:

EMS:

Proper Shipping Name:

Notes: Is not subject to current regulations for transportation of hazardous goods (GGVS/ADR, GGVE/RID, IMDG, IATA/ICAO).

15. Regulatory

Notes: This product must be not labeled in accordance with EEC directive 67/548 and 99/45.

16. Other information

The information herein is believed to be correct as of the date hereof but is provided without warranty of any kind. The recipient of our product is responsible for ensuring that,
where applicable, existing laws and guidelines are observed.
Special permission has been granted in accordance with EU Directive 99/45, Article 9, which permit small packages of up to 125 ml or g containing materials that are harmful to health or irritant to be unlabelled with the hazard identification information given in the safety data sheet.

7-10

7.2.3 C3 Fluid Pack

Safety Data Sheet

Roche

Date: 23.11.2001 Date of printing: 23.11.2001 Page 1 of 3

1. Name of substance/preparation and company

1.1 Commercial product: **Fluid Pack C3**
BP2655

Cat.-No.: 3144038

1.2 Company: Roche Diagnostics GmbH
Sandhoferstr. 116
D-68305 Mannheim
Tel. ++49-621-7590
Information obtainable from: ++49-621-759-2763 or ++49-621-759-4848

1.3 In Emergencies: Central Works Security Roche Diagnostics GmbH ++49-621-759-2211
Centre for Detoxification: Mainz ++49-6131-232466-232467
München ++49-89-19240

2. Composition/Information on constituents

Kit contains:

Reagent 1 (1x): Classification: not necessary
Contains: No hazardous substances in reportable quantities.

Reagent 2 (1x): Classification: Xi; R: 36/38; S: 26-37.
Contains: <0,7 % (CAS-Nr.: 0001333-83-1; T; C; R: 23-24-25-34; S: 36/37-45).

Reagent 3 (1x): Classification: not necessary
Contains: 2,1 % (CAS-Nr.: 0007631-90-5; Xn; R: 20/22-31; S: 1-13-22).

Reagent 4 (1x): Classification: not necessary
Contains: No hazardous substances in reportable quantities.

Notes: Is to be classified according to EEC directive 67/548 and 88/379 as hazardous.

Classification: Irritant

3. Hazards identification

Warnings: 36/37/38 Irritating to eyes, respiratory system and skin

Notes:

4. First aid measures

First aid: Eye contact: Promptly wash eyes with water for at least 15 minutes, if necessary seek medical advice.
Skin contact: Wash skin with water throuogh.
Ingestion: In case of overdose seek medical advice.

Instructions for physician: Symptomatic treatment by a physician.

5. Fire-fighting measures

Extinguishing media: No restriction

Thermal decomposition: Dangerous decomposition is not anticipated.

6. Accidental release measures

After spillage: Wash off small quantities with plenty of water. Take up larger quantities with fluid binders and dipose off in a suitable manner.

Absorbent material: No restriction.

Damage limitation: Special measures to limit damage are not necessary.

7-11

Safety Data Sheet

Roche

Date: 23.11.2001 Date of printing: 23.11.2001 Page 2 of 3

Commercial product: **Fluid Pack C3**
BP2655

7. Handling and storage

7.1 Handling: Substance or preparation itself does not burn.
No special requirements.

7.2 Storage: Store at room temperature.

Do not store with: No restriction

8. Exposure controls/personal protection

TLV: undefined
Respiratory protection:
Eye protection: prot.glasses
Hand protection: One-way gloves
Hygiene: Wash hands before breaks and at the end of the work.

9. Physical and chemical properties

Reagent 1

Physical state: liquid
Miscible with water: yes
pH: 7
Flash point: not determined

Reagent 2

Physical state: liquid
Miscible with water: yes
pH: 3,5
Flash point: not determined

Reagent 3

Physical state: liquid
Miscible with water: yes
pH: 6,8
Flash point: not determined

Reagent 4

Physical state: liquid
Miscible with water: yes
pH: 12
Flash point: not determined

10. Stability and reactivity

Hazardous Reactions: None known when used appropriately.

Hazardous decomposition products: None

11. Toxicological information

Reagent 3:

LD50 oral	2000	mg/kg	(rat)
LD50 intraperitoneal	650	mg/kg	(rat)
LD50 skin	not known		
LD50 inhal	not known		

7-12

Safety Data Sheet

Roche

Date: 23.11.2001 Date of printing: 23.11.2001 Page 3 of 3

Commercial product: **Fluid Pack C3**
BP2655

12. Ecological information

13. Disposal considerations

Waste disposal route: Used reagent can be disposed off in waste water in accordance with local regulations.

Disposal of emptied packs: Dispose of empty packs via local recycling or waste disposal routes - if necessary, clean them beforehand.

14. Transport information

RID/ADR:
ICAO/IATA: UN-No.:
IMDG-Code: MFAG:
EMS:

Proper Shipping Name:

Notes: Is not subject to current regulations for transportation of hazardous goods (GGVS/ADR, GGVE/RID, IMDG, IATA/ICAO).

15. Regulatory

Notes: This product must be labeled in accordance with EEC directive 67/548 and 88/379.
Hazard symbol: Xi
Warnings: see section 3.
Precautions: 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
37 Wear suitable gloves

16. Other information

The information herein is believed to be correct as of the date hereof but is provided without warranty of any kind. The recipient of our product is responsible for ensuring that, where applicable, existing laws and guidelines are observed.
Special permission has been granted in accordance with EU Directive 88/379, Article 9, which permit small packages of up to 125 ml or g containing materials that are harmful to health or irritant to be unlabelled with the hazard identification information given in the safety data sheet.

7-13

7.3 Calibration procedure

7.3.1 BG / ISE calibration

The Roche OMNI C analyzer uses a patented, novel approach for the simultaneous calibration of PCO_2, pH, Na^+, K^+, Ca^{2+} and Cl^- sensors, using only two aqueous base solutions, eliminating the need of any gas supply system and its related disadvantages.

The base solution C2 contains defined quantities of the acid component of a pH buffer system and electrolytes. The base solution C1 contains quantities of carbonate and bicarbonate, electrolytes and the base components of the pH-buffer system. The chemical nature of these solutions, the initial concentrations of their components and packaging make them insensitive to usual exposure to ambient air during on-shelf or in-use storage with small changes being negligible for the purpose of calibration.

The partial pressure of CO_2, pH-value and the actual concentrations of the various electrolytes are calculated using traditional chemical and mathematical formulas. The calibration method is controlled by the simple measurement of conductivity of these two solutions (C1 and C2) prior to mixing.

The mec$PAO_2{}^t \leq PO_2$ otherwise $PAO_2{}^t = PO_2{}^t$ighly accurate because the actual mixture is determined exactly by measurement of the conductivity of the resulting mixture. The two solutions contain highly different electrolyte concentrations. The conductivity of the individual solutions relative to the conductivity of the mixture of these solutions can be reliably used to determine the actual mixing ratio.

After determining the mix ratio, use common chemical and mathematical formulas to calculate the PCO_2 and the pH value and all ISE parameters.

There is no systematic difference in the calibration principle between the prior methods and this method.

Reliability of the calibration procedure

- The precision of the mixing unit was determined to be better than 0.1%.
- The mixing unit is calibrated every 24 hrs.

The actual concentration of the base solutions are determined precisely for each production lot and coded on the bottles.

7.3.2 Calibration of the conductivity system as part of the mixing system

The conductivity system is calibrated with calibration solutions C1 and C2 to determine the actual mixing ratio in correlation with the mixing system.

7.3.3 tHb/SO2 module calibration

Factory calibration

The tHb modules undergo a so-called factory calibration before being installed in the instruments. During this calibration, differences in optical properties caused by mechanical tolerances and surface properties are separately determined for each module. This is carried out in an external device using special calibration fluids. The established measurement values are permanently stored in a memory module (EEPROM) in the tHb/SO_2 module. These stored measurement values are read out by the instrument for each measurement and used to calculate the final results.

1P Calibration

The 1-point calibration of the tHb/SO_2 module is carried out before each measurement with Mix1. It allows for incorporating possible changes or contaminations of the complete optical system into the calculation of the final result. If certain limit values are exceeded, measurement values are no longer issued and the user is asked to perform a system cleaning.

7.4 Parameters and calculations

7.4.1 Conversion table for units

The Roche OMNI C provides an array of useful parameters, which are calculated from the measurement values of each sample. Refer to the following table for an explanation of the symbols used in the equations. Unless otherwise noted, all measured values used in the equations are at 37 °C.

ctO_2, $avDO_2$, $ctCO_2$	1 vol.%	= 1 ml/dL	= 0.4464 mmol/L
ionized calcium (Ca^{2+})	1 mmol/L	= 4.008 mg/dL	
tHb	1 g/dL	= 10 g/L	= 0.6202 mmol/L
air pressure, PCO_2, PO_2	1 mmHg	= 1.3333 mbar	= 0.1333 kPa
Temperature	°F	$= \frac{9}{5} \cdot T[°C] + 32$	
	°C	$= \frac{5}{9} \cdot T[°F] - 32$	

7.4.2 Units of calculated parameters

Designation	Format & unit 1 [Std]	Format & unit 2	Format & unit 3
H^+	xxx.x nmol/L		
$cHCO_3$	xxx.x mmol/L		
$ctCO_2$(P)	xxx.x mmol/L	xxx.x mL/dL	xxx.x Vol%
BE	xxx.x mmol/L		
BE_{act}	xxx.x mmol/L		
BE_{ecf}	xxx.x mmol/L		
BB	xxx.x mmol/L		
SO_2	xxx.x %		
SO_2(c)	xxx.x %		
$P50$	xx.x mmHg	xx.xx kPa	
pH_{st}	x.xxx [-]		
$cHCO_3^-{}_{st}$	xxx.x mmol/L		
PAO_2	xxx.x mmHg	xx.xx kPa	
$AaDO_2$	xxx.x mmHg	xx.xx kPa	
$avDO_2$	xx.xx Vol%	xx.xx mL/dL	xx.xx mmol/L
Qs/Qt	xx.xx %	xx.xx [-]	
nCa^{2+}	xx.xx mmol/L	xx.xx mg/dL	
AG	xxx.x mmol/L		
pH^t	x.xxx [-]		
H^{+t}	xxx.x nmol/L		

PCO_2^t	xxx.x mmHg	xx.xx kPa	
PO_2^t	xxx.x mmHg	xxx.xx kPa	
PAO_2^t	xxx.x mmHg	xx.xx kPa	
$AaDO_2^t$	xxx.x mmHg	xx.xx kPa	
a/AO_2^t	xx.x %	xx.x [-]	
RI^t	xx %	x.xx [-]	
Hct (c)	xx.x %	x.xxx [-]	
OER	xx.xx %	xx.xx [-]	

7.4.3 Equations[1]

H^+

Concentration (activity) of hydrogen ions in plasma.

$$H^+ = 10^{(9\text{-}pH)} \quad \text{[nmol/L] (5)}$$

$cHCO0_3^-$

Bicarbonate concentration in plasma.

$$cHCO_3^- = 0.0307 \cdot PCO_2 \cdot 10^{(pH-6.105)} \quad \text{[mmol/L] (6)}$$

$ctCO_2(P)$

Total concentration of CO_2 in plasma, the sum of dissolved CO_2 and bicarbonate.

$$ctCO_2(P) = cHCO_3^- + (0.0307 \cdot PCO_2) \quad \text{[mmol/L] (7)}$$

BE

The base deviation of the blood results from a calculation to determine the titratable base of the blood, which in principle is measured by titration of the blood with a strong acid or base to a pH of 7.4 with PCO_2 = 40 mmHg at 37 °C.

$$BE = (1 - 0{,}014 \cdot tHb) \cdot [(1{,}43 \cdot tHb + 7{,}7) \cdot (pH - 7{,}4) - 24{,}8 + cHCO_3^-] \quad \text{[mmol/L] (10)}$$

BE_{act} see equation 43!

[1] Equations taken from "Acid-Base-Hb-ISE-Parameter", Rev. 13, Sept. 2002

BE_{ecf}

The base deviation of extracellular fluid is a quantity that reflects only the non-respiratory components of acid-base balance.

$$BE_{ecf} = 16{,}2 \cdot (pH - 7{,}4) - 24{,}8 + cHCO_3^- \quad \text{[mmol/L] (11)}$$

BB

The buffer base is the concentration of buffering anions which is available in whole blood to buffer strong acids and consists mainly of protein anions and bicarbonate. Of the protein anions, hemoglobin is the most significant.

$$BB = BE + 41{,}7 + 0{,}42 \cdot tHb \quad \text{[mmol/L] (12)}$$

SO_2 (c)

Functional oxygen saturation uses blood gas values:

$$SO_2(PO_2, pH, P50, a/f, BE) = \frac{Q}{Q+1} \cdot 100 \quad [\%]$$

with :

$$lgQ = 2{,}9 \cdot lgPO_2^{\,k} + F1 \cdot 10^{-F2 \cdot PO_2^{\,k}} - F3$$

$$lgPO_2^k = lgPO_2 + 0{,}48 \cdot (pH - 7{,}4) - lg(\frac{P50}{26{,}7}) + 0{,}0013 \cdot BE$$

Adult :

$P50 = 26{,}7$

$F1 = 1{,}661 \qquad F2 = 0{,}074 \qquad F3 = 4{,}172$

Fetal :

$P50 = 21{,}5$

$F1 = 1{,}3632 \qquad F2 = 0{,}0533 \qquad F3 = 4{,}113$

P_{50}

The oxygen partial pressure at half saturation, P_{50}, is defined as the PO_2 value for a given blood sample at which 50% of the hemoglobin is saturated with oxygen. The actual P_{50} value can be calculated from interpolation after measurement of the actual oxygen saturation if a blood sample is tonometered with oxygen so that an oxyhemoglobin of 50% is achieved (pH value = 7.4 and PCO_2 = 40 mmHg). The Roche OMNI C enables the derivation of the P_{50} from SO_2%, PO_2 and pH. If a measured SO_2% is not available, the P_{50} value may be input via keyboard.

For adult hemoglobin:

$$P50 = 26{,}7 \cdot 10^{\left(\lg PO O_2 - \lg PO_2{}^k\right)}$$

with :

$$\lg PO_2{}^k = \frac{(\lg Q + F3)}{2.9}$$

$$Q = \frac{SO_2}{100\,\% - SO_2}$$

[mmHg] (14)

F3 = 4.172

For fetal hemoglobin:

$$P50 = 25.0 \cdot 10^{(\lg PO_2{}^k + \lg PO_2)}$$

with :

$$\lg PO_2{}^k = \frac{(\lg Q + F3)}{2.9}$$

$$Q = \frac{SO_2}{100\% - SO_2}$$

[mmHg] (14)

F3 = 4.113

ctO_2

Oxygen content is the sum of oxygen bound to hemoglobin as O2Hb and the amount of oxygen dissolved in the plasma.

[vol.%] (15)

$$ctO_2(PO_2, SO_2, \text{tHb}) = 1{,}39 \cdot \frac{SO_2}{100} \cdot \text{tHb} + 0{,}00314 \cdot PO_2$$

If PO_2 is not available, ctO_2 is calculated with PO_2 = 90 mmHg.

SO_2 see equation 13!

$ctCO_2(B)$

Total concentration of CO_2 in the blood, the sum of the total CO_2 in plasma and the red blood cell (erythrocyte) fluid (ERY).

[mmol/L] (16)

$$ctCO_2(B) =$$

$$0{,}000768 \cdot PCO_2 \cdot \text{tHb} \cdot (1 + 10^{(pH_{ERY} - pK_{ERY})}) + ctCO_2(P) \cdot (1 - \frac{\text{tHb}}{33{,}8})$$

with :

$$pH_{ERY} = 7{,}19 + 0{,}77 \cdot (pH - 7{,}4) + 0{,}035 \cdot (1 - \frac{SO_2}{100})$$

$$pK_{ERY} = 6{,}125 - \lg(1 + 10^{(pH_{ERY} - 7{,}84 - 0{,}06 \cdot \frac{SO_2}{100})})$$

SO_2 see equation 13!

A correct calculation of the calculated value is possible only after measurement of a whole blood sample in the sample type setting "blood".

pH_{st}

Standard pH value of the blood is defined as the pH value of a blood sample which has been equilibrated at 37 °C with a gas mixture having a PCO_2 = 40 mmHg.

[pH-unit] (17)

$$pH_{st} =$$

$$(0.8262 - 0.01296 \cdot \text{tHb} + 0.006942 \cdot \text{BE}) \cdot \lg(0.025 \cdot PCO_2) + pH$$

$cHCO_3^-{}_{st}$

Standard bicarbonate of the blood, defined as the plasma bicarbonate concentration in blood which has been equilibrated at 37 °C with a gas mixture having a PCO_2 = 40 mmHg.

$$cHCO_3^-{}_{st} = 10^{(pH_{st}-6.022)} \quad \text{[mmol/L] (18)}$$

This formula is simplified and does not take into consideration ctHb and SO_2 contents.

PAO_2

The alveolar oxygen tension is used for the calculation of several parameters used in the evaluation of oxygenation and ventilation and can be estimated with the following equation:

For t unequal to 37°C see equation 34!

$$PAO_2 = (P_{tota} - 47)\cdot FIO_2 - PACO_2 \cdot \left[FIO_2 + \frac{1 - FIO_2}{R} \right] \quad \text{[mmHg] (20)}$$

$PACO_2 = PaCO_2$ (alveolar PCO_2)

for $PAO_2 \geq PO_2$; otherwise $PAO_2 = PO_2$

R = gas exchange ratio = respiratory quotient

$AaDO_2$

The alveolar to arterial oxygen tension gradient (PAO_2 - PaO_2) is the

difference between the alveolar oxygen partial tension, estimated above, and the measured oxygen partial tension of arterial blood.
For t unequal to 37°C see equation 35

$$AaDO_2 = (PAO_2 - PaO_2) \quad \text{[mmHg] (21)}$$

a/AO_2

Arterial-alveolar oxygen partial pressure ratio.

For t unequal to 37°C see equation 36

$$a/AO_2 = \frac{PaO_2}{PAO_2} \cdot 100 \quad \text{[\%] (22)}$$

avDO$_2$

The arterial-venous oxygen tension ratio.

$$\mathrm{avDO_2} = c\mathrm{tO_2(a)} - c\mathrm{tO_2(v)} \quad \text{[vol\%] (23)}$$

Calculate ctO$_2$(a) and ctO$_2$(v) according to the calculation for ctO$_2$ for arterial and venal blood.

Calculation only, under the following conditions:

- same patient number for both measurements
- maximum time interval = 30 minutes
- sample type either arterial or venous blood

RI

The respiratory index is calculated as the ratio of the alveolar-arterial oxygen tension gradient to the arterial oxygen tension.

$$\mathrm{RI} = \frac{(P\mathrm{AO_2} - P\mathrm{aO_2})}{P\mathrm{aO_2}} \cdot 100 \quad \text{[\%] (24)}$$

nCa^{2+}

The ionized calcium value standardized to pH = 7.40.

$$\mathrm{nCa^{2+}(pH = 7{,}4)} = \mathrm{Ca^{2+}} \cdot 10^{\mathrm{F5 \cdot (pH - 7{,}4)}} \quad \text{[mmol/L] (28)}$$

Blood: F5 = 0.22

Serum/plasma: F5 = 0.24

AG

The anion gap is a calculated parameter used to express the difference in concentrations of major cations and anions in the blood specimen.

$$\mathrm{AG} = \mathrm{Na^+} + \mathrm{K^+} - \mathrm{Cl^-} - c\mathrm{HCO_3^-} \quad \text{[mmol/L] (29)}$$

pH^t

pH corrected to patient temperature other than 37 °C.

$$pH^t = pH - [0.0147 + 0.0065 \cdot (pH - 7.4)] \cdot (t - 37) \quad \text{[pH-unit] (30)}$$

H^{+t}

Concentration of hydrogen ions corrected to patient temperature other than 37 °C.

$$H^{+t} = 10^{(9-pH^t)} \quad \text{[nmol/L] (31)}$$

PCO_2^t

PCO_2 value corrected to patient temperature other than 37 °C.

$$PCO_2{}^t = PCO_2 \cdot 10^{0.019 \cdot (t-37)} \quad \text{[mmHg] (32)}$$

PO_2^t

PO_2 value corrected to patient temperature other than 37 °C.

$$PO_2{}^t = PO_2 \cdot 10^{\left[\frac{5.49 \cdot 10^{-11} \cdot PO_2{}^{3.88} + 0.071}{9.72 \cdot 10^{-9} \cdot PO_2{}^{3.88} + 2.30}\right] \cdot (t-37)} \quad \text{[mmHg] (33)}$$

PAO_2^t

Alveolar oxygen tension corrected to patient temperature other than 37 °C.

$$PAO_2{}^t = \left(P_{total} - PH_2O^t\right) \cdot FIO_2 - PACO_2{}^t \cdot \left[FIO_2 + \left(1 - \frac{FIO_2}{R}\right)\right] \quad \text{[mmHg] (34)}$$

for

with $PH_2O^t = 47 \cdot 10^{[0{,}0237 - 0{,}0001 \cdot (t-37)] \cdot (t-37)}$

$AaDO_2^t$

Alveolar to arterial oxygen tension difference corrected to patient temperature other than 37 °C.

$$AaDO_2{}^t = PAO_2{}^t - PaO_2{}^t \quad \text{[mmHg] (35)}$$

a/AO$_2^t$

Arterial-alveolar oxygen partial pressure ratio at the patient's temperature.

$$a/AO_2^t = \frac{PaO_2^t}{PAO_2^t} \times 100 \quad [\%] \ (36)$$

RI^t

Respiratory index corrected to patient temperature other than 37 °C.

$$RI^t = \frac{(PAO_2^t - PaO_2^t)}{PaO_2^t} \times 100 \quad [\%] \ (37)$$

Hct(c)

Hct as a function of *c*tHb.

$$Hct = tHb \times \frac{F}{100} \quad [-] \ (40)$$

Default value of F=3.00 (input range: 2.70 to 3.30)

MCHC

Mean corpuscular hemoglobin concentration.

$$MCHC = \frac{tHb}{Hct} \quad [g\ Hb / dL\ Ery] \ (41)$$

Only displayed as a calculated value if both values are measured.

This factor is the reciprocal value as it is used in hematology.

BE$_{act}$

Base deviation at actual oxygen saturation.

$$BE_{act} = (1 - 0{,}0143 \times tHb) \times [(1{,}63 \times tHb + 9{,}5) \times (pH - 7{,}4) - 24{,}26 + cHCO_3^-] + 0{,}2 \times tHb \times (1 - \frac{SO_2}{100}) \quad [mmol/L] \ (43)$$

Osmolality

$$Osm = 2 \times (Na^+ + K^+) + 3 \times (Ca^{2+} + Mg^{2+}) + Glu + Urea$$

[mOsm/kg] (44)

Default values:
K = 4.3 mmol/L, iCa = 1.25 mmol/L, iMg = 0.6 mmol/L, Glu = 4.5 mmol/L, Urea = 5 mmol/L

Explanation:

Na: if no measurement value is available, no osmolality is calculated

K: if no measurement value is available, the default value is used for the calculation

Ca^{2+}: see K!

OER

Oxygen extraction ratio

$$OER = \frac{(ctO_2(a) - ctO_2(v))}{ctO_2(v)} \times 100$$

[%] (45)

ctO_2 from equation (15)

Q_t

Difference of oxygen concentration between alveolar and mixed venous blood

$$Q_t = ctO_2(A) - ctO_2(v) = (ctO_2(a) - ctO_2(v)) + 1{,}39 \times tHb \times \frac{SaO_2}{100} + (PAO_2 - PaO_2) \times 0{,}00314$$

[%] (46)

P/F index

PaO_2/FIO_2 ratio

$$P/F\ Index = \frac{PaO_2}{FIO_2}$$

[-] (47)

8 Appendix

8.1 Description of various reports 8-1

8.1.1 Measurement report 8-1

8.1.2 QC protocol 8-2

8.1.3 Levey-Jennings diagram 8-3

8.1.4 Calibration report 8-4

8.1.5 Sensor status report 8-5

8.2 Clinical significance 8-6

8.2.1 pH 8-6

8.2.2 PCO_2 8-7

8.2.3 PO_2 8-7

8.2.4 Sodium 8-7

8.2.5 Potassium 8-8

8.2.6 Chloride 8-10

8.2.7 Ionized calcium 8-10

8.2.8 tHb (total hemoglobin concentration) 8-12

8.2.9 Hematocrit (Hct) 8-13

8.2.10 Oxygen saturation (SO_2) 8-13

8.3 AutoQC module (option) 8-15

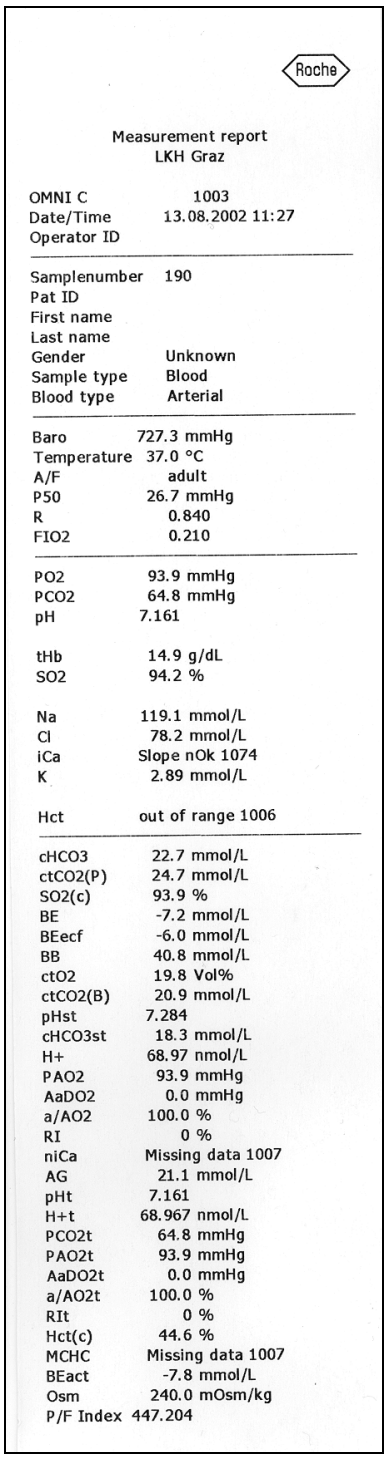
8.3.1 Instrument description / Function 8-15

8.3.2 Inserting the mats 8-16

8 Appendix

8.1 Description of various reports

8.1.1 Measurement report



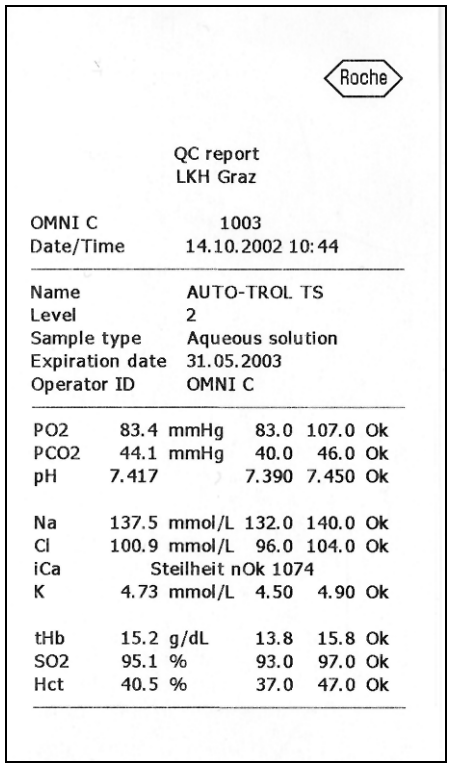
Roche

Measurement report
LKH Graz

OMNI C	1003
Date/Time	13.08.2002 11:27
Operator ID	
Samplenumber	190
Pat ID	
First name	
Last name	
Gender	Unknown
Sample type	Blood
Blood type	Arterial
Baro	727.3 mmHg
Temperature	37.0 °C
A/F	adult
P50	26.7 mmHg
R	0.840
FIO2	0.210
PO2	93.9 mmHg
PCO2	64.8 mmHg
pH	7.161
tHb	14.9 g/dL
SO2	94.2 %
Na	119.1 mmol/L
Cl	78.2 mmol/L
iCa	Slope nOk 1074
K	2.89 mmol/L
Hct	out of range 1006
cHCO3	22.7 mmol/L
ctCO2(P)	24.7 mmol/L
SO2(c)	93.9 %
BE	-7.2 mmol/L
BEecf	-6.0 mmol/L
BB	40.8 mmol/L
ctO2	19.8 Vol%
ctCO2(B)	20.9 mmol/L
pHst	7.284
cHCO3st	18.3 mmol/L
H+	68.97 nmol/L
PAO2	93.9 mmHg
AaDO2	0.0 mmHg
a/AO2	100.0 %
RI	0 %
niCa	Missing data 1007
AG	21.1 mmol/L
pHt	7.161
H+t	68.967 nmol/L
PCO2t	64.8 mmHg
PAO2t	93.9 mmHg
AaDO2t	0.0 mmHg
a/AO2t	100.0 %
RIt	0 %
Hct(c)	44.6 %
MCHC	Missing data 1007
BEact	-7.8 mmol/L
Osm	240.0 mOsm/kg
P/F Index	447.204

Fig. 1

8.1.2 QC protocol



Roche

QC report
LKH Graz

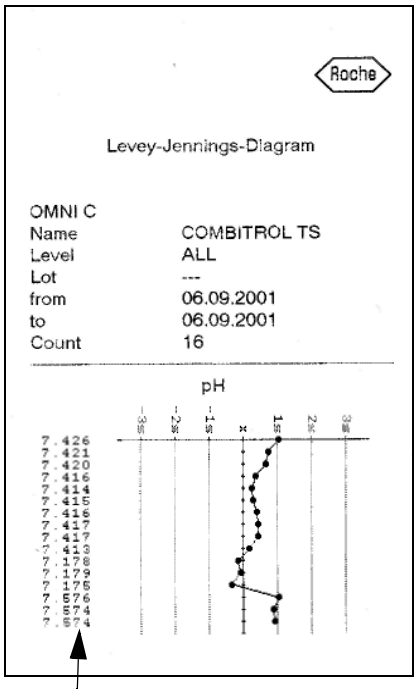
OMNI C 1003
Date/Time 14.10.2002 10:44

Name AUTO-TROL TS
Level 2
Sample type Aqueous solution
Expiration date 31.05.2003
Operator ID OMNI C

PO2	83.4	mmHg	83.0	107.0	Ok
PCO2	44.1	mmHg	40.0	46.0	Ok
pH	7.417		7.390	7.450	Ok
Na	137.5	mmol/L	132.0	140.0	Ok
Cl	100.9	mmol/L	96.0	104.0	Ok
iCa	Steilheit nOk 1074				
K	4.73	mmol/L	4.50	4.90	Ok
tHb	15.2	g/dL	13.8	15.8	Ok
SO2	95.1	%	93.0	97.0	Ok
Hct	40.5	%	37.0	47.0	Ok

Fig. 2

8.1.3 Levey-Jennings diagram



QC measurement values

Fig. 3

X..... mean value

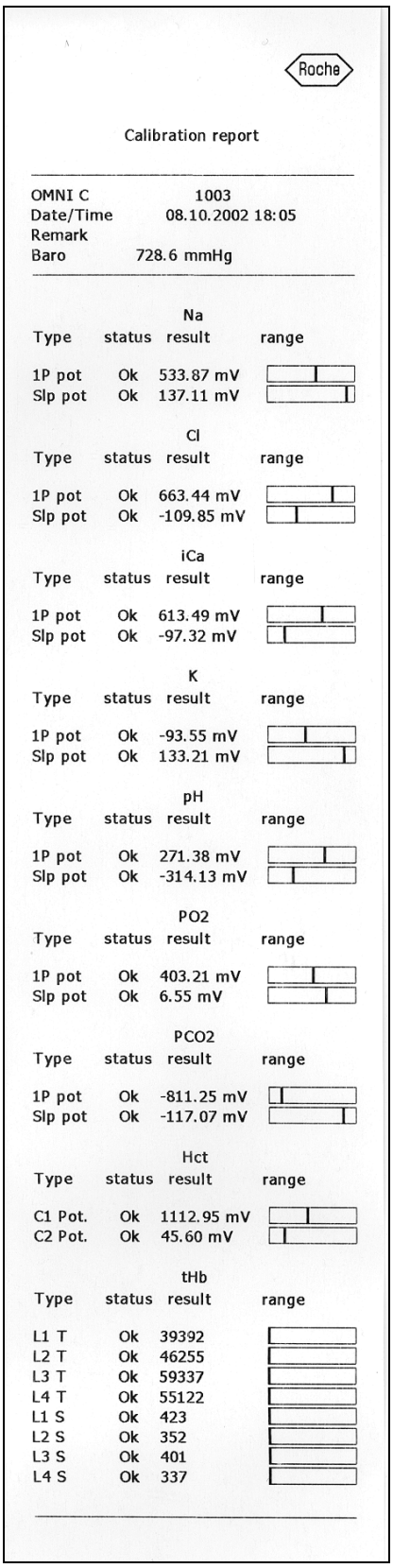
s..... standard deviation

1s..... QC measurement value lies outside of X ± 1s

2s..... QC measurement value lies outside of X ± 2s

3s..... QC measurement value lies outside of X ± 3s

8.1.4 Calibration report



Roche

Calibration report

OMNI C 1003
Date/Time 08.10.2002 18:05
Remark
Baro 728.6 mmHg

Na

Type	status	result	range
1P pot	Ok	533.87 mV	
Slp pot	Ok	137.11 mV	

Cl

Type	status	result	range
1P pot	Ok	663.44 mV	
Slp pot	Ok	-109.85 mV	

iCa

Type	status	result	range
1P pot	Ok	613.49 mV	
Slp pot	Ok	-97.32 mV	

K

Type	status	result	range
1P pot	Ok	-93.55 mV	
Slp pot	Ok	133.21 mV	

pH

Type	status	result	range
1P pot	Ok	271.38 mV	
Slp pot	Ok	-314.13 mV	

PO2

Type	status	result	range
1P pot	Ok	403.21 mV	
Slp pot	Ok	6.55 mV	

PCO2

Type	status	result	range
1P pot	Ok	-811.25 mV	
Slp pot	Ok	-117.07 mV	

Hct

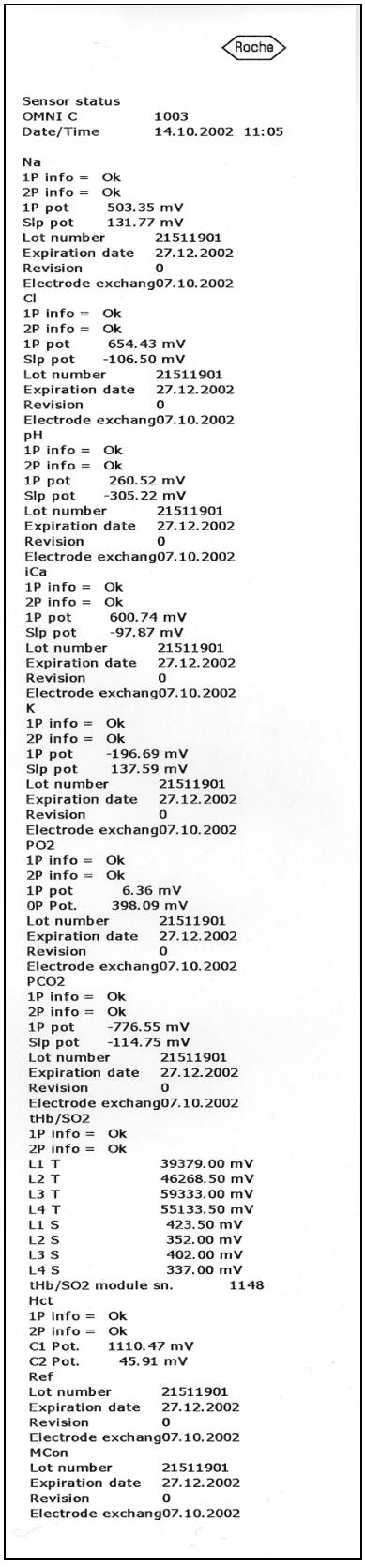
Type	status	result	range
C1 Pot.	Ok	1112.95 mV	
C2 Pot.	Ok	45.60 mV	

tHb

Type	status	result	range
L1 T	Ok	39392	
L2 T	Ok	46255	
L3 T	Ok	59337	
L4 T	Ok	55122	
L1 S	Ok	423	
L2 S	Ok	352	
L3 S	Ok	401	
L4 S	Ok	337	

Fig. 4

8.1.5 Sensor status report



Roche

Sensor status
OMNI C 1003
Date/Time 14.10.2002 11:05

Na
1P info = Ok
2P info = Ok
1P pot 503.35 mV
Slp pot 131.77 mV
Lot number 21511901
Expiration date 27.12.2002
Revision 0
Electrode exchang07.10.2002
Cl
1P info = Ok
2P info = Ok
1P pot 654.43 mV
Slp pot -106.50 mV
Lot number 21511901
Expiration date 27.12.2002
Revision 0
Electrode exchang07.10.2002
pH
1P info = Ok
2P info = Ok
1P pot 260.52 mV
Slp pot -305.22 mV
Lot number 21511901
Expiration date 27.12.2002
Revision 0
Electrode exchang07.10.2002
iCa
1P info = Ok
2P info = Ok
1P pot 600.74 mV
Slp pot -97.87 mV
Lot number 21511901
Expiration date 27.12.2002
Revision 0
Electrode exchang07.10.2002
K
1P info = Ok
2P info = Ok
1P pot -196.69 mV
Slp pot 137.59 mV
Lot number 21511901
Expiration date 27.12.2002
Revision 0
Electrode exchang07.10.2002
PO2
1P info = Ok
2P info = Ok
1P pot 6.36 mV
0P Pot. 398.09 mV
Lot number 21511901
Expiration date 27.12.2002
Revision 0
Electrode exchang07.10.2002
PCO2
1P info = Ok
2P info = Ok
1P pot -776.55 mV
Slp pot -114.75 mV
Lot number 21511901
Expiration date 27.12.2002
Revision 0
Electrode exchang07.10.2002
tHb/SO2
1P info = Ok
2P info = Ok
L1 T 39379.00 mV
L2 T 46268.50 mV
L3 T 59333.00 mV
L4 T 55133.50 mV
L1 S 423.50 mV
L2 S 352.00 mV
L3 S 402.00 mV
L4 S 337.00 mV
tHb/SO2 module sn. 1148
Hct
1P info = Ok
2P info = Ok
C1 Pot. 1110.47 mV
C2 Pot. 45.91 mV
Ref
Lot number 21511901
Expiration date 27.12.2002
Revision 0
Electrode exchang07.10.2002
MCon
Lot number 21511901
Expiration date 27.12.2002
Revision 0
Electrode exchang07.10.2002

Fig. 5

8.2 Clinical significance[1]

8.2.1 pH

The pH value of blood, serum or plasma may be the single most valuable factor in the evaluation of the acid-base status of a patient. The pH value is an indicator of the balance between the buffer (blood), renal (kidney) and respiratory (lung) systems, and one of the most tightly controlled parameters in the body. The causes of abnormal blood pH values are generally classified as:

pH < 7.35

- primary bicarbonate deficit – metabolic acidosis
- primary hypoventilation – respiratory acidosis

pH > 7.45

- primary bicarbonate excess – metabolic alkalosis
- primary hyperventilation – respiratory alkalosis

An increase in blood, serum or plasma pH (alkalosis) may be due to increased plasma bicarbonate, or a feature of respiratory alkalosis because of an increased elimination of CO_2 due to hyperventilation.

A decrease of the pH value (acidosis) in blood, serum or plasma may occur due to an increased formation of organic acids, a decreased excretion of H^+ ions (buffered with phosphate and ammonium ions) in certain renal disorders, an increased acid intake such as in salicylate poisoning or loss of alkaline body fluids. Respiratory acidosis is the result of decreased alveolar ventilation and may be acute, as the result of pulmonary edema, airway obstruction or medication, or maybe be chronic, as the result of obstructive or restrictive respiratory diseases.

Standard values

arterial blood:..... 7.35 - 7.45

venous blood: ..... 7.31 - 7.41

[1] 1. Oswald Müller-Plathe "Säure-Basen-Haushalt und Blutgase",
2. revised and expanded edition, 1982.
3. Wirnt Rick, "Klinische Chemie und Mikroskopie", 6. revised and expanded edition, 1989.

8.2.2 PCO_2

The PCO_2 value of arterial blood is used to assess how well the body eliminates carbon dioxide in relation to the metabolic rate of CO_2 production. An arterial PCO_2 below the normal range is termed respiratory alkalosis and indicates hypocapnia, a condition caused by increased alveolar ventilation such as hyperventilation.

An arterial PCO_2 above the normal range is termed respiratory acidosis and indicates hypercapnia, a sign of hypoventilation and failure, resulting from cardiac arrest, chronic obstructive lung disease, drug overdose, or chronic metabolic acid-base disturbances.

Standard values

arterial blood:	35 - 45 mmHg
venous blood:	41 - 51 mmHg

8.2.3 PO_2

The PO_2 value in arterial blood is the main factor in calculating arterial oxygenation.

Values below the normal range (arterial hypoxia) are normally caused by blockages in the lung and respiratory tract as well as in the blood circulatory system (for example: bronchial obstruction, vascular disturbances, lessened cardiac function, increased need for oxygen, anatomical cardiac defect, lower level of inspired O_2). In general, PO_2 values over 100 mm Hg do not contribute significantly to the oxygen level because with a normal hemoglobin concentration of 80-100 mm Hg PO_2, a saturation level of 97% has already been achieved.

Standard values

arterial blood:	> 80 mm Hg
venous blood:	30 - 40 mm Hg

8.2.4 Sodium

The fast majority of sodium in organisms is located in the extracellular area (about 97%).

Even with greatly varying supply with nourishment, the sodium concentration in serum is subject to strong regulation. In the kidneys, sodium is glomerularly filtered and most of this (about 60 - 70 %) is reabsorbed in the proximal tubule.

The most important function of the sodium is to maintain constant osmolality in the extracellular fluid. For that reason, the levels of sodium and water are closely interrelated. A normal serum-sodium level provides no information about the amount of cations in the organism. If values lie in the standardized area, there may be a pronounced hypohydration or hyperhydration of the tissue. Conversely, an increased, respectively a decreased sodium concentration is found in serum due to a loss or gain of water when there is a normal level of sodium.

An increased sodium level in serum occurs when there is:

- a decreased supply of liquid
- increased loss of water
- through the kidneys - diabetes insipidus
  -renal diabetes insipidus
  -osmotic diuresis (for example, mannitin fusions)

  infectious diseases of the intestine (especially dysentery and cholera)
- excessive supply of hypertonic saline solution (infusion therapy dosed too high)
- increase of aldosterone-induced sodium reabsorption
  - primary hyperaldosteronism (CONN syndrome)
  - secondary hyperaldosteronism

Reduced sodium level in serum occurs following:

- excessive supply of liquid without sufficient absorption of sodium
- excessive water supply with normal level of sodium in the organism (for example: congestive heart failure)
- disturbance of sodium reabsorption caused by aldosterone deficiency
  - suprarenal gland insufficiency (M. ADDISON)
  - adrenogenital syndrome with saline loss (aldosterone insufficiency with high grade enzyme defect)

Normal values

Adult:	135 - 148 mmol/L
Newborn:	134 - 144 mmol/L
Child:	138 - 144 mmol/L

8.2.5 Potassium

About 97% of potassium within the organism is intracellular. Transport into the cells is regulated by the Na/K ATPase localized in the cell membrane. Only about 3% of the potassium is contained in the extracellular fluid. Potassium is glomerularly filtered and most of it (about 90%) is reabsorbed in the proximal tubule and in Henle's loop. Reabsorption or excretion in the distal tubulus is influenced especially by aldosterone and the blood pH value.

Due to the high intracellular concentration of potassium, the serum potassium values do not always reflect the potassium level of the organism. Therefore, the data obtained from the serum may be interpreted only with careful consideration of the patient's clinical situation and acid-base status. Consider the following examples: diabetic coma, during which the flow of potassium into the cell is reduced due to the lack of insulin, and acute intoxication with heart glycosides with accompanying inhibition of the Na/K ATPase membrane. In both cases exists, despite a more or less greatly increased serum potassium level, intracellular potassium deficiency.

Increased potassium concentration in serum occurs during:

- decreased excretion through the kidneys
  - acute and chronic kidney insufficiency (especially pronounced with oliguria and anuria)
  - Aldosterone deficiency with suprarenal gland insufficiency (M. ADDISON)
  - dosage of potassium-saving diuretic
  - oral potassium substitution with (possibly unknown) mild limitation of kidney functions
- displacement between intracellular and extracellular potassium
  - severe insulin deficiency
  - intoxication with heart glycosides
  - severe acidosis
    (each 0.1 reduction of the blood pH results in a rise in potassium of 0.4 to 1.2 mmol/L serum)
  - malignant hyperthermia
- release of potassium during massive cell death
  - hemolytic crisis
  - transfusions with cold or very cold blood
  - cytostatic therapy for leukemia and others
  - burns
  - severe soft tissue injuries

Hypokalemia is observed during:

- gastrointestinal potassium losses
  - laxative abuse
  - massive diarrhea
  - fistulas in the area of the gastrointestinal tract
  - villous papillary adenoma
  - VERNER-MORRISON syndrome (pancreatic cholera)
- increased renal excretion
  - primary hyperaldosteronism (CONN syndrome)
  - secondary hyperaldosteronism
  - cirrhosis of the liver
    (caused by decreased aldosterone breakdown)
  - therapy with loop diuretics and thiazides
  - CUSHING
  - Aldosterone producing suprarenal gland carcinoma
  - overdose of mineral corticoids
  - renal tubular acidosis
- displacement between intracellular and extracellular potassium
  - severe alkalosis
  - insulin therapy for diabetic coma
    (potassium substitution required!)

Normal values

Adult:	3.5 – 5.0 mmol/L
Newborn:	3.7 – 5.9 mmol/L
Child:	3.4 – 4.7 mmol/L

8.2.6 Chloride

Chloride is the most important anion in bodily fluids. Chloride is located – like sodium – mostly in the extracellular area. Erythrocytes represent the highest intracellular content. The concentration of chloride in serum, like the level of sodium, is held constant within tight limits in healthy people. Chloride is glomerulary filtered in the kidneys and is tubularly reabsorbed by passively following the sodium.

Chloride may be exchanged for bicarbonates during disturbances to the acid/base status, causing chloride to adopt the additional task (in addition to maintaining the isotones in the extracellular area) of working with sodium to regulate the acid/base status.

Changes to the chloride and sodium concentrations in serum usually occur in parallel.

Exceptions to this occur during disturbances to the acid/base status caused by the previously mentioned exchange of chloride for bicarbonates as well as during massive chloride loss with gastric juices during extended periods of vomiting (hypochloremic alkalosis).

Normal values[1]

Adult:	98 - 107 mmol/L
Newborn:	98 - 113 mmol/L

8.2.7 Ionized calcium

Approximately 99% of calcium in the human body is localized in bone substance – mostly in the form of hydroxylapatite.

About 1% of the cations are located in the extracellular area. Only very small amounts exist intracellularly; the calcium ions here act especially as activators for numerous enzymes and play a role in the effect mechanism of hormones.

It is possible to exchange calcium in the extracellular fluid for that in bones.

In addition, hydroxylapatite serves as a reserve holder from which calcium can be rapidly mobilized when needed.

[1] Tietz Textbook of Clinical Chemistry. Eds Burtis & Ashwood ER. Saunders 3rd ed. Philadelphia, USA 1999

Calcium is present in plasma in 3 forms:

About 50% are ionized and biologically active,

about 40% are bound to proteins (especially albumin) and

about 10% are present in complex bonds with citrate, phosphate, bicarbonate, lactate, and others.

Protein bonding is dependent on the concentration of albumen in plasma and on the pH level of the blood:

With lower total albumen and an acidic pH level, fewer calcium ions are bound, causing the ionized proportion to increase. This also explains why, despite a low level of calcium in serum during severe acidosis (due to chronic kidney insufficiency), tetanic reactions do not occur.

The portion of calcium suitable for ultrafiltration (ionized and complex bound) is glomerularly filtered in the kidneys and up to 95 - 99% reabsorbed in the proximal and distal tubule.

A small portion of the calcium can also be excreted via the intestine.

The regulation of calcium exchange is closely related to the regulation of the phosphate level. Therefore, the concentrations of both substances in serum and the excretion with urine should always be seen and judged in relationship to each other.

The level of calcium in plasma is decisive for calcium-phosphate exchange. Three hormones play roles in the regulation. They affect the maintenance of the extracellular calcium concentration via the reabsorption of calcium ions from the intestine, the release or storage processes in bones and the extent of the renal excretion.

Parathormone and 1.25-dihydroxycholecalciferol:

- lead to an increase of the calcium concentration in plasma

Calcitonin:

- reduces the level of calcium

Increased concentrations of calcium in serum occur during:

- disturbances to the hormonal regulation of primary and tertiary hyperparathyreoidism
- increased release from the bones
  - osteolysis through bone metastasis
  - plasmocytome
  - paraneoplastic symptom
    (through ectopic production of parathormone or similar substances or prostaglandin E2)
  - long-lasting immobilization
- vitamin D intoxication within the scope of therapeutic measures
- Sarcoidosis

Reduced calcium levels in serum will be noticed as a result of:

- insufficient calcium reabsorption
  - undernourishment
  - mal-absorption syndrome
  - vitamin D3 deficiency
  - deficiency of 1.25-dihydroxycholecalciferol
  - chronic kidney insufficiency
  - hypoparathyreoidism
  - hypomagnesium
- greatly decreased concentration of albumen in the serum (Note: ionized calcium is in the normal range!)
  - nephrotic syndrome
  - cirrhosis of the liver
- acute pancreatitis

Normal values

Adult:	1.09 – 1.33 mmol/L
Child:	1.10 – 1.50 mmol/L

8.2.8 tHb (total hemoglobin concentration)

Hemoglobin is the main component of erythrocytes. It serves as the vehicle for transportation of oxygen within the bloodstream and each gram/dL of hemoglobin can carry 1.39 mL of oxygen. The oxygen combining capacity of the blood is directly proportional to the hemoglobin concentration rather than to the number of red blood cells (RBC), because some red cells contain more hemoglobin than the others.

Although oxygen transport is the main function of hemoglobin, it also serves as an important buffer in the extracellular fluid.

Decreased hemoglobin values appear in connection with hemolytical reactions caused by transfusions of untolerated blood, but can also be caused by a loss of blood or a number of other factors.

Increased levels are found in hemoconcentration of the blood, chronic obstructive pulmonary disease and congestive heart failure.

ctHb gives valuable information in an emergency situation if interpreted not in an isolated fashion but in conjunction with other pertinent laboratory data.

tHb is used to screen for disease associated with anemia, to determine the severity of anemia, to follow the response to treatment for anemia and to evaluate polycythemia.

Normal values

Women:	12 - 16 g/dL
Men:	13.5 - 17.5 g/dl
Newborns:	4 - 20 g/dL

8.2.9 Hematocrit (Hct)

Hematocrit is the volume fraction taken up by red blood cells. The Hct can be expressed as percentage or fraction.

Reduced Hct values are an indication for anemia (together with a simultaneous reduction of ctHb and RBC) of leukemia, hypothyroidism, cirrhosis, acute massive blood loss and with hemolytic reactions due to transfusions with incompatible blood, incompatibility with certain chemicals, infectious and physical agents.

Increased Hct values can be associated with polycythemia, erythrocytosis and heavy loss of water and with shock.

Normal values[1]

Women:	37 - 47%
Men:	40 - 54%
Newborns:	50 - 62%

For patients with heavy blood loss, for massive infusion therapies and for difficult operations, e.g. open-heart surgery, determining the hematocrit value by means of the conductivity method applied in the Roche OMNI C can lead to incorrect results. The measured hematocrit value can be significantly too low, particularly with infusions with protein-free electrolyte solutions or with the use of hyperosmolar solutions. This artificially lowered hematocrit value can lead to an unnecessarily premature decision for transfusion.

In such cases, it is recommended either to directly measure the hematocrit (microcentrifuge or PCV) or to indirectly determine it using the measurement of the total hemoglobin.

8.2.10 Oxygen saturation (SO_2)

Oxygen saturation is the measured portion of the oxyhemoglobin in total hemoglobin.

Reference values:

Adults:	in art. blood 95 – 98 %; in venal blood about 73 %
Newborns:	in art. blood 40 – 90 %;

[1] Tietz Textbook of Clinical Chemistry. Eds Burtis & Ashwood ER. Saunders 3rd ed. Philadelphia, USA 1999

The measurement of $_SO_2$ is used to judge oxygenation, usually in connection with other parameters, for example PO2, PCO2 and hemoglobin.

For the monitoring of patients with possible hypoxia[1], SO_2 levels are > 90 % assumable.

In principle, SO_2 measurements are better than estimated values (O_{2sat}); however, when using SO_2 measurements during the presence of abnormal hemoglobins (for example carboxyhemoglobin[2]) incorrect results may arise [for example, assuming a comatose patient with 15 % COHb, an SO2 value of 95 % may be shown, although in reality the level of oxyhemoglobin (FO2Hb) is only 80 % (100 % is the summation of all hemoglobins)]. For this reason, the NCCLS suggests evaluation of the dyshemoglobins[3] instead of a clinical evaluation of a single SO_2 value].

1 Indicative for a decreased level of oxygen in blood

2 COHb

3 COHb, MetHb, SulfHb

8.3 AutoQC module (option)

If the Roche OMNI C features an AutoQC module, it can only be assembled and installed by customer service.

CAUTION: If the Roche OMNI C is transported with installed AutoQC module, it must not be used for carrying purposes!

The AutoQC module is a unit that enables the Roche OMNI C to automatically perform quality control measurements.

In the AutoQC module, quality control materials are used in special glass ampoules (capacity of 120 pieces; up to 6 different materials and levels can be used at the same time) that feature proven storage capability, instrument compatibility and analytic reliability. At each instant previously programmed by the user, an ampoule is automatically opened, the control agent is aspirated into the measurement module measured. The mechanical and electronic components used for this purpose as well as the selected fluid transport are designed so that highest ruggedness and stability are ensured. The measured quality control sample is not subject to any cross interferences through improper operation, which achieves a significantly lower variability and a significantly improved statement about the quality of the instrument than a manual performance of the quality control measurement.

8.3.1 Instrument description / Function

The AutoQC module consists of the ampoule block and a needle which penetrates the bottom of the ampoule after positioning by motors (X and Y direction or Z direction) and aspirates the QC fluid from the ampoule.

The ambient temperature of the ampoule is measured using the AQC temperature sensor.

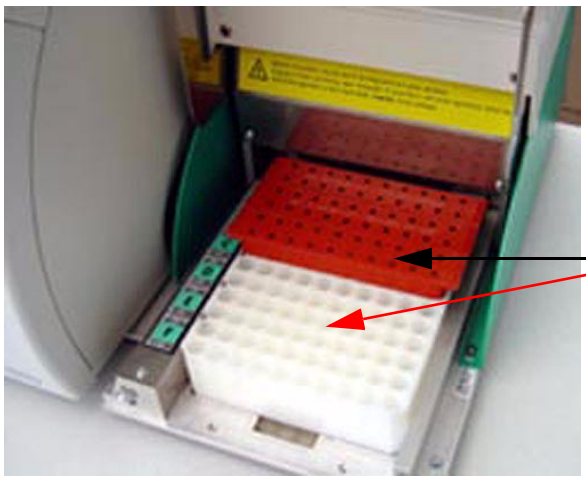


Fig. 6

CAUTION: The AutoQC module may only be operated with closed cover.

Possible danger of injuries from moving parts and glass fragments!

8.3.2 Inserting the mats

Insert the mats into the ampoule block as follows:

- Define the AutoQC material to be measured (see Instructions for Use, chapter 5 "**Quality Control**," section „**Materials setting**").
- Open the cover of the AutoQC module.
- If necessary, remove the empty mat from the desired position of the ampoule block.

If individual ampoules should be stuck in the white ampoule block after the removal of the ampoule mats, do not forget that these opened ampoules can break if they are grasped, thus creating a danger of injuries.

Protect your hands by using gloves and pulp!

Dispose of mats with opened ampoules within the time period indicated on the packaging text according to local regulations.

CAUTION: Danger of spillage!

•Remove a full mat (20 ampoules) from the packaging.

- Define the desired position (position A_F) for the new mat.
  The corresponding description can be found in chapter 3 "**Operating States**," section "**Settings – QC Material – AutoQC Materials**"!
- Turn the mat so that the neck of the ampoule points down. Shake the mat and ensure that the neck of the ampoules is free of air bubbles (see Fig. 2).

Fig. 7

- Place the mat in the defined position of the ampoule block so that the ampoules are no longer visible.
- Repeat the process in the same way for all additional mats.
- Close the cover of the AutoQC module.
- The AutoQC module is now ready.

Index

A

Activate / deactivate for calibration 3-28
Activate / deactivate for measurement 3-28
Aggregates 3-14
Appendix 8-1
ASTM transfer 3-42
Auto preparation routines 3-7
Automatic patient ID 3-60
Automatic routines 3-5
AutoQC 3-62
  Copying a time entry 3-35
  Description 8-15
  position test 3-15

B

Barcode 3-22
Baro sensor 3-19
Bibliography 4-15
Brightness level 3-59

C

Calculation values 3-29
Calibration 3-54
Calibration DB overview 3-54
Calibration DB query 3-54
Calibration intervals 3-34
Calibration report 3-54, 8-4
Calibrations 3-26
Chloride 8-10
Clean sample port module 3-4
Clean screen 3-4
Cleaning all tubing 3-5
Cleaning counter 3-61
Clinic info 3-61
Clinical significance
  Chloride 8-10
  Hematocrit (Hct) 8-13
  Ionized calcium 8-10
  Oxygen saturation (SO_2) 8-13
  PCO_2 8-7
  pH 8-6
  PO_2 8-7
  Potassium 8-8
  Sodium 8-7
COM 1 3-42
COM 2 3-44
Conditioning cycle 3-7
Contact paths 3-16
Control sensors 3-16
Correlation to other Methods
  Calcium 4-9
  Chloride 4-9
  Hematocrit 4-10
  PCO_2 4-8
  pH 4-8
  $PO2$ 4-8
  Sodium 4-8
  Total hemoglobin 4-9
  SO_2 4-10
Correlations 3-32

D

Data export 3-69
Date 3-33
Date and time 3-33
Default settings 3-52
Delete data 3-70
Description of various reports 8-1

E

Economy mode 3-34
Enter measurement info 3-53
Enter patient info 3-53
Equations 7-17
Event report 3-55
Export log data 3-10
External patient query 3-62

F

Fehlerbehebung 5-1
Flash file system 3-23
Fluid actions 3-7

G

Group administration 3-64

H

Hematocrit (Hct) 8-13
Hotline Info 3-58

I

Input values 3-46
Installation 3-9
Instrument data 3-55
Instrument DB overview 3-55
Instrument DB query 3-55
Interfaces 6-1

Internal cleaning of sample path 3-5
Intervals 3-33

L

Language 3-57
Levey-Jennings diagram 8-3
Limitations 4-13
  Blood gases 4-13
  Electrolytes 4-13
  General 4-13
  tHb / SO_2 4-14
Linearity
  Electrolytes in RNA CVC123 4-7
  Electrolytes in serum 4-6
  Tonometered whole blood 4-6
  Total Haemoglobin and hematocrit in whole blood 4-7
Linearity, Precision and Recovery
  Whole blood 4-6
Load program 3-8

M

Maintenance 3-11
Maintenance scheduler 3-36
Mandatory input 3-2, 3-47
Manual economy mode 3-8
MBX board 3-24
Measurement and input values 3-29
Measurement report 3-48, 8-1
Measuring data 3-46
Measuring sensors 3-25
Miscellaneous settings 3-28
Monitoring sensors 3-17
Multirules 3-29

N

Network 3-40

O

Operating modes 3-1
Other units 3-60

P

Parameter
  display ranges 3-54
Parameters and calculations 7-16
password 3-2
Patient database 3-54
Patient DB overview 3-55
Patient DB query 3-54
PC components 3-19
PCMCIA card 3-12, 3-23
Performance data 4-1
Peristaltic pump 2-7, 3-14
Permissible standard deviation 3-31
pH -> H+ 3-31
Potassium 8-8
Power rating - power supply 2-9
Prepare Calibration Solution C1 3-7
Prepare Calibration Solution C2 3-7
Prepare cleaning solution 3-7
Prepare conditioning solution 3-7
Prepare PO_2 zero solution 3-7
Printer 3-21
Printer settings 3-59

Q

QC 3-54
QC consequences 3-30
QC DB query 3-54
QC protocol 8-2
QC report 3-54
QC times 3-34
QC unlock 3-30

R

Reference / critical ranges 3-32
Reference electrode 3-7
Result screen 3-47

S

Sample sensors 3-16
Screen 3-19
Security level 3-63
Set ranges 3-39
Shutdown 3-9
Sodium 8-7
Software communication 3-8
Software shutdown 3-8
Speaker 3-59
Specific performance characteristics
  Reproducibility 4-1
System 3-3
System description 2-1

T

Temperature control 3-18
Test 3-13
tHb / SO_2 module 7-3
Theoretical foundations 7-1

Timeouts 3-38
Tools 3-6
Touch screen 3-20

U

Units 3-28
Units of calculated parameters 7-16
User management 3-63

V

Valves 3-14

W

Wash AutoQC (option) 3-5
Wash sample path 3-5
Washing and cleaning 3-4
Waste container sensor 3-17